Final Environmental Impact Statement (EIS) for the

PROPOSED RULE:

Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

October 2015

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

October 30, 2015

Subject: Proposed Rule: Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption - Final Environmental Impact Statement

To: All interested parties

The U.S. Food and Drug Administration (FDA) has issued a Final Environmental Impact Statement (Final EIS) for the Proposed Rule—Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Proposed Rule).

The purpose of proposing this rule is to minimize the risk of serious adverse health consequences or death, including those actions reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards.

FDA published a Draft EIS for public review on its Web site on January 12, 2015. The Final EIS was prepared and is being circulated consistent with the Council for Environmental Quality Regulations for Implementing the National Environmental Policy Act of 1969 (NEPA), pursuant to 40 CFR § 1502.19, and FDA regulations for Environmental Impact Considerations, pursuant to 21 CFR § 25.42.

The Final EIS includes responses to substantive comments on the Draft EIS, and revisions to the EIS based on comments and where we determined that additional clarification was needed.

For further information on the Produce Safety Proposed Rule, please visit the FDA Web site: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm.

Sincerely,

Michael R. Taylor
Deputy Commissioner for Foods
and Veterinary Medicine

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Abstract

Final Environmental Impact Statement

Proposed Rule: Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

U.S. Food and Drug Administration

The Food Safety Modernization Act of 2011 (FSMA) directs the U.S. Food and Drug Administration (FDA) to build a new food safety system based on the public health principle of comprehensive prevention, an enhanced focus on risk-based resource allocation, and partnership across the public and private sectors to minimize food and feed hazards from farm to table. As such, FSMA gives FDA the public health mandate to establish standards for the adoption of modern food safety prevention practices by those who grow, process, transport, and store food. Through FSMA, FDA has proposed seven rules for stakeholders (food producers, suppliers, distributors) to follow in the supply chain that would protect public health by promoting safe, sanitary standards that, when implemented, would minimize or prevent food safety hazards. One of the Proposed Rules—*Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (Produce Safety Proposed Rule or PS PR)—is the subject of this Final Environmental Impact Statement (EIS).

The purpose of proposing this rule is to minimize the risk of serious adverse health consequences or death, including those actions reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards.

FDA announced its intent to prepare an EIS and began the EIS scoping period in August 2013. This EIS, prepared in accordance with the National Environmental Policy Act and developed by the FDA in cooperation with the U.S. Department of Agriculture, assesses the environmental (including human) and related socioeconomic impacts based on "potentially significant provisions" of the PS PR, and alternatives to the provisions that were considered. The No Action Alternative is assessed in this EIS as a basis for comparison, to determine the environmental impacts associated with existing conditions (current practices, laws, and procedures) if the PS PR were not implemented. FDA received public comments on the tentative conclusions reached in the Draft EIS, and considered public input and incorporated responses in developing this Final EIS. For more information on this Final EIS, please use one of the following methods:

Dockets Management Branch (HFA-305)
Docket No. FDA-2014-N-2244
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD USA 20852
Internet:
FDA's Division of Dockets Management at
http://www.regulations.gov

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Executive Summary

The U.S. Food and Drug Administration (FDA), an Operating Division within the U.S. Department of Health and Human Services (HHS), is responsible for protecting public health by ensuring the safety and security of human and veterinary drugs, biological products, medical devices, tobacco, foods, cosmetics, and products that emit radiation (FDA, 2013a). In compliance with the Congressional mandate contained within the FDA Food Safety Modernization Act (FSMA), FDA proposed to implement a final rule aimed at minimizing the risk of contamination of fresh produce during growing, harvesting, packing, and/or holding of fresh produce for human consumption. This proposal is based on our analysis and conclusions that the final rule and the provisions contained therein will be beneficial to human health by reducing the incidence of foodborne illness.

Congress specifically mandated through FSMA that " . . . the Secretary [of HHS, and by delegation, FDA], in coordination with the Secretary of Agriculture and representatives of State departments of agriculture (including with regard to the national organic program established under the Organic Foods Production Act of 1990), and in consultation with the Secretary of Homeland Security, shall publish a notice of proposed rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death" (section 419(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. § 350h(a)(1)(A)). Further, FSMA mandates that "the Secretary [of HHS, and by delegation, FDA] . . . adopt a final regulation to provide for minimum science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits or vegetables, that are raw agricultural commodities, based on known safety risks, which may include a history of foodborne illness outbreaks" (section 419(b)(1) of FFDCA (21 U.S.C. § 350h(b)(1))).

ES.1 Purpose and Need

The purpose of establishing requirements for the growing, harvesting, packing, and holding of produce for human consumption is to minimize the risk of serious adverse health consequences or death, including those requirements reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards.

Each year foodborne diseases result in an estimated 48 million people (1 in 6 Americans) within the U.S. becoming ill, 128,000 hospitalizations, and 3,000 deaths, according to recent data from the Centers for Disease Control and Prevention (CDC) (CDC, 2014a). This is a significant burden to public health that is largely preventable. The estimated annual cost of foodborne illnesses attributable to produce is $1.865 billion (FDA, 2014b). The estimated number of annual foodborne illnesses attributable to produce that would be covered by the rule, based on FDA 2013 estimates, is 2,703,144 (FDA, 2013b).

Congress recognizes the unique challenges faced by FDA in the area of food safety in the 21st century and, in 2011, enacted FSMA to meet those challenges. FSMA directs FDA to build a new food safety system based on the public health principle of comprehensive prevention, an enhanced focus on risk-based resource allocation, and partnership across the public and private sectors to minimize food and feed hazards from farm to table (FDA, 2012b). As such, FSMA gives FDA the public health mandate to establish standards for the adoption of modern food safety prevention practices by those who grow, process, transport, and store food. FSMA also provides FDA the authorities and oversight tools aimed at providing solid assurances that those practices are being carried out by the food industry on a consistent, on-going basis (FDA, 2014a).

ES.2 Background on the proposed rule

In determining the scope of the proposed rule, FDA found that although there is the potential for chemical, physical, or radiological contamination of produce, rarely do the chemical and physical hazards associated with produce suggest a risk of serious adverse health consequences or death for individuals that would consume the product. FDA also found that the presence of radiological hazards in foods is a rare event and that consumer exposure to harmful levels of radionuclide hazards, outside of catastrophic events, is very low (Beru, 2012; FDA, 2011a; UNSCEAR, 2008). Therefore, the agency is not proposing specific standards for these hazards in the Produce Safety Proposed Rule (PS PR) (see 78 Fed. Reg. 3504 at 3524). Conversely, FDA's analysis of available foodborne illness outbreak data estimates 2,703,144 annual foodborne illnesses attributable to produce that would be covered by the proposed rule (FDA, 2013b). Therefore, the PS PR focuses on setting enforceable standards that are reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards and provide reasonable assurances that produce is not adulterated on account of these hazards.

As part of the rulemaking process, FDA conducted a draft qualitative assessment of risk (QAR) associated with growing, harvesting, packing, and holding of produce (hereinafter referred to as the Draft Qualitative Assessment of Risk or Draft QAR) (FDA, 2013c). The Draft QAR provides a scientific evaluation of potential adverse health effects resulting from human exposure to hazards in produce, with a focus on public health risk associated with on-farm microbial contamination of produce. The Draft QAR includes (1) Hazard Identification, (2) Hazard Characterization, (3) Exposure Assessment, and (4) Risk Characterization. This document helped to inform FDA on the risk management decisions the Congressional mandate directs FDA to make, in part, by focusing on those biological hazards that present a risk of serious adverse health consequences or death to the consumer (FDA, 2013c).

Produce commodities are susceptible to exposure to biological hazards before, during, and after harvest. The likelihood of exposure to such hazards varies by commodity and by other factors such as cultivation and production systems, the supply chain infrastructure, and environmental considerations; however, the sources of potential contamination during growing, harvesting, packing, and holding are common across commodities (FDA, 2013c).

Over the years, FDA has obtained information that provides insight regarding the routes of contamination during growing, harvesting, packing, and holding produce safely on farms. Based on findings of the Draft QAR; observations during inspections, investigations, and surveillance activities; and other available information, FDA grouped the possible routes of contamination into five pathways: water, soil amendments, animals, worker health and hygiene, and equipment and buildings (FDA, 2013c).

FDA has tentatively concluded it is appropriate to use a regulatory framework based on practices, procedures, and processes associated with growing, harvesting, packing, and holding of all covered produce.[1] FDA considered and rejected the option to develop a framework that, based solely on a history of outbreaks or illnesses associated with specific commodities, would be applicable to individual commodities or classes of commodities. FDA's reasoning for adopting an integrated approach focusing on practices and procedures (*e.g.*, that are linked to common, on-farm routes of contamination), rather than a commodity-specific approach, is discussed in Chapter 1.6 of the EIS.

On January 4, 2013, FDA released for public comment a proposed rule to establish minimum science-based *Standards for Growing, Harvesting, Packing, and Holding Produce for Human Consumption*. This rule is one of seven proposed rulemakings that lays the cornerstone of the prevention-based, modern food safety system that is needed to help protect human health from foodborne illness. FDA published this proposed rule in the Federal Register on January 16, 2013 ("the 2013 proposed rule"), for codification in 21 CFR Part 112 (78 Fed. Reg. 3504). On March 20, 2013, FDA issued a notice to correct technical errors and errors in reference numbers cited in the 2013 proposed rule (78 Fed. Reg. 17155). Subsequent to the publication of the 2013 proposed rule, extensive information received in public comments led to significant changes in FDA's thinking. As a result, on September 29, 2014, FDA issued a supplemental notice of proposed rulemaking ("the supplemental proposed rule"), amending certain specific provisions of the 2013 proposed rule (79 Fed. Reg. 58434). Taken together, these publications constitute FDA's proposed standards for the PS PR. FDA has reviewed public comments to the supplemental proposed rule as well as comments submitted by the public in response to the Draft EIS, and is using this information to develop a Produce Safety Final Rule.

The 2013 proposed rule was accompanied by a categorical exclusion under 21 CFR 25.30(j). Subsequent to the publication of the 2013 proposed rule and after reviewing public comments to the proposed rule, FDA reconsidered the application of the categorical exclusion and determined that the preparation of an EIS was necessary. FDA published a notice of its intent to prepare an EIS, and notice opening the EIS scoping period, in the Federal Register on August 19, 2013 (78 Fed. Reg. 50358). On April 4, 2014, FDA held a public scoping meeting to provide public attendees and interested parties with background on the 2013 proposed rule, to identify those provisions that may significantly affect the quality of the human environment, to identify alternatives FDA should consider, and to further request public comment.

FDA considered the comments received during scoping and on the 2013 proposed rule and supplemental proposed rule, and subsequently prepared the Draft EIS, which was published on

[1] Covered produce is produce that would be subject to the requirements of proposed 21 CFR Part 112 in accordance with §§ 112.1 and 112.2 and refers to the harvestable or harvested part of the crop.

FDA's Web site on January 12, 2015. The Notice of Availability (NOA) for the Draft EIS was published in the *Federal Register* on January 14, 2015 (80 Fed. Reg. 1852). On February 10, 2015, FDA held a public meeting where presenters provided public testimony.

FDA received comments on the Draft EIS from interested parties, industry groups, consumer groups, and a Native American Indian Tribe. FDA considered each comment. Responses to substantive comments are included in Appendix E. The U.S. Department of Agriculture (USDA) submitted feedback and input on the Draft EIS, and FDA incorporated USDA's edits when preparing the Final EIS. However, USDA did not review the Final EIS prior to publication. EPA submitted its review of the Draft EIS in accordance with EPA's authorities under NEPA and Section 309 of the Clean Air Act (see Appendix F).

A more detailed summary of the public involvement process in found within Chapter 1.8 of the Final EIS.

ES.3 Scope of the EIS

FDA proposed under the PS PR to implement standards for the growing, harvesting, packing, and holding of produce commodities, with some exceptions. Produce commodities not exempt from nor otherwise outside the scope of the rule are considered "covered produce."

The provisions of the PS PR, if finalized, would apply to both domestically grown and imported produce. FDA intends to evaluate its obligations under Executive Order (EO) 12114, "Environmental Effects Abroad of Major Federal Actions," related to this action in a document that is separate from this EIS.

The scope of this EIS includes the conterminous United States, Alaska, and Hawaii. In addition, areas outside the 50 states examined in this EIS include Puerto Rico, U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands (hereinafter "EIS geographical areas"). This EIS also considers potentially significant transboundary effects associated with implementing the rule.[2]

A major source for information on where produce commodities are grown domestically is compiled through the USDA National Agriculture Statistics Service (NASS) Census of Agriculture surveys, which are conducted nationally every five years. Using USDA NASS 2012 survey data published in 2014 (cited as USDA NASS, 2014a), FDA prepared a map showing where in the U.S. covered produce is grown (see Figure ES-1). Figure ES-1, which also appears in chapter 1.7 as Figure 1.7-4, serves as a foundation for FDA's analysis within this EIS.

Using this map as a foundation, FDA is able to better compare the relationship between where covered produce is grown and physical resources, such as surface water, groundwater, wildlife and other resources that are presented in Chapter 3 of the EIS, and the impact that covered activities have on these resources, discussed in Chapter 4 of the EIS. The regions depicted in Figure ES-1

[2] Transboundary effects, as discussed here, are those that cross borders with other countries (*i.e.*, Canada and Mexico).

are based upon 27 Land Resource Regions that were previously identified by the USDA Natural Resources Conservation Service (NRCS). The USDA NRCS subdivided the country into these regions because they share similar soils, climate, and vegetation or crop types (USDA NRCS, 2006).

Of note, Figure ES-1 illustrates that high densities of covered produce are grown within Regions B, C, D, L, and U; however, other regions are important as they relate to different resource components studied in the EIS. Produce acreage on the map is represented by dots on the map with each dot representing 1,000 acres of cropland.

With respect to the EIS geographical areas, USDA NASS 2012 survey data were available only for Puerto Rico. In addition, a review of 2007 NASS survey data revealed that with a possible few exceptions (individual farms), most farms in the EIS geographical areas would be excluded from the rule because the estimated average annual revenue reported for produce sales was below the proposed $25,000 threshold for produce farms (proposed 21 CFR 112.3(c)). As a result, of the EIS geographical areas, only Puerto Rico is included within the analysis of this EIS. Puerto Rico is not shown in Figure ES-1 or Figure 1.7-4; however, FDA did include farms in Puerto Rico in the Preliminary Regulatory Impacts Analysis (PRIA) (FDA, 2013b), so estimates of total number of covered farms, acreage, and cost include Puerto Rico.

We described in the Draft EIS that the PS PR contains four potentially significant provisions that, if finalized, may significantly affect the quality of the human environment: (subpart E) Standards directed to agricultural water, (subpart F) Standards directed to BSAs of animal origin and human waste, (subpart I) Standards directed to domesticated and wild animals, and (subpart A) General provisions (under which the aggregate impacts of all provisions of the PS PR, including those that were deemed potentially significant and those that were excluded from more detailed analysis in Chapter 2.2, are considered if the farm is covered under subpart A). These potentially significant provisions form the foundation for our environmental impact analysis (see ES.6, or Final EIS Chapter 4) (21 CFR proposed Part 112, as amended in the supplemental proposed rule).

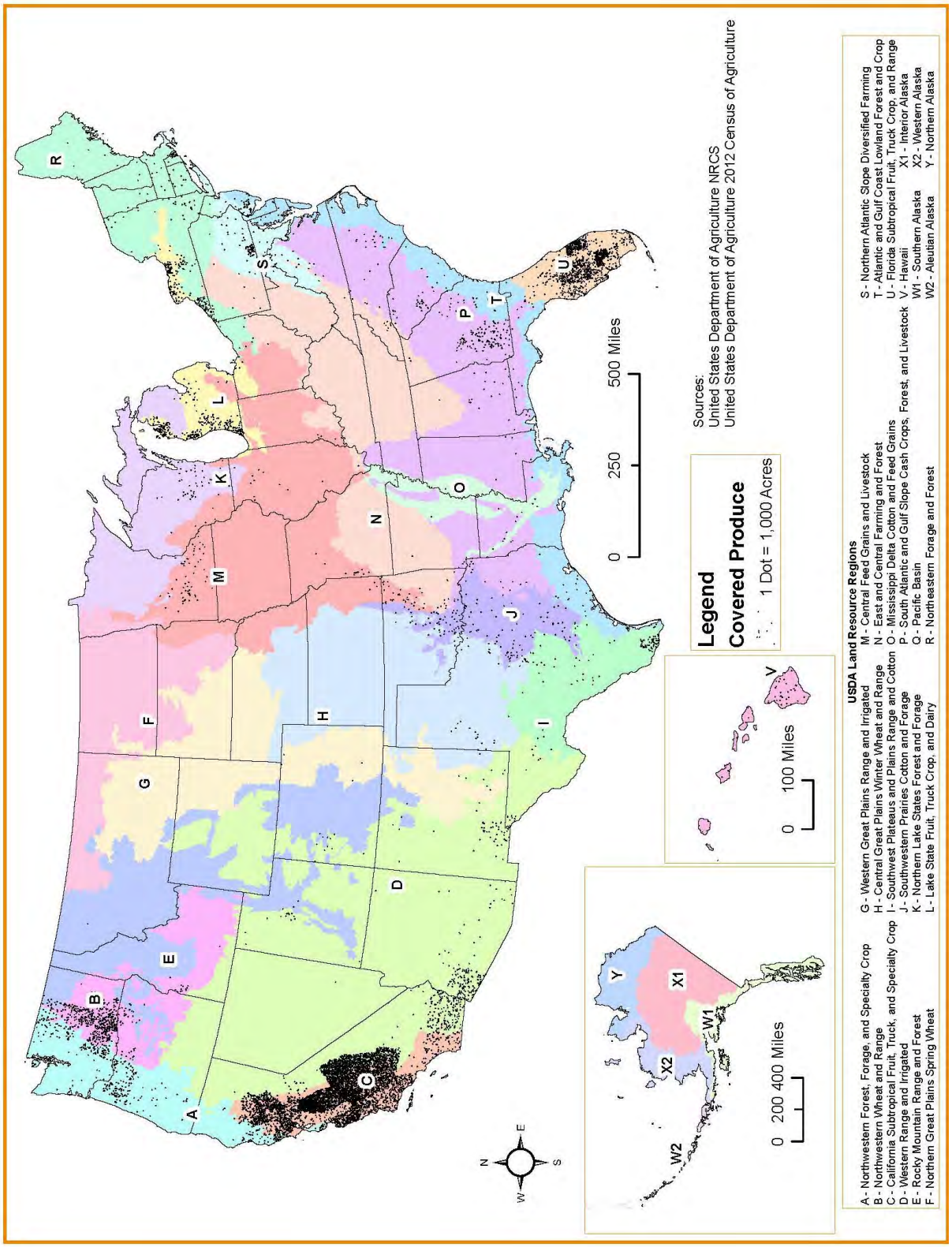
We identified in the EIS that there are management decisions related to compliance with these potentially significant provisions that a grower may make that may result in environmental effects that may significantly impact the human environment, and include effects which may be later in time or farther removed in distance, but are still reasonably foreseeable (40 CFR 1508.8). For example, if agricultural water is unsafe for use, then the grower may make a management decision that may include treating the water source, changing the irrigation mechanism, changing the water source, ceasing to grow covered produce, or adding a post-harvest rinse to account for microbial removal (more discussion on management decisions is found in the following section titled, “Management decisions and impact analysis”).

We further identified a number of factors that could influence a grower’s management decision in response to the requirements in a produce safety final rule. These factors included the availability of “safe” water or an alternative “safe” water supply (including the ability to apply flexibility options provided in the PS PR), costs associated with accessing the water, availability and costs associated with soil amendments, the extent to which grazing animals or wildlife may contaminate

covered produce, climate and weather, soil quality conditions, topography, demand and prices for certain agricultural commodities, and the type of crop being grown. These factors vary widely across the nation and may not be the same among neighboring farms. Therefore, we determined it is not feasible for an EIS to assess individual (site-specific) potential environmental variables. Data and information are not available concerning these local conditions affecting specific individual growers. Instead, we relied on a geographic framework at a regional and national level for our analysis in this EIS, focusing our analysis on those regions where covered produce is grown (for a map of the regions see Figure ES-1). Where possible, we also considered environmental impacts at a state level when data and information were available. We received public comment on this approach. Our response to these comments is found in Appendix E, under the heading "Scope of the EIS: Analysis of Localized/Regional Impacts."

See Chapter 1.9 of the Final EIS for a full discussion on the scope of the EIS.

Figure ES-1. Regions where covered produce in the U.S. is grown



Implementation of the final rule with respect to this EIS would focus on a sub-set of farming operations found within the geographical scope because the rule, if finalized as proposed, would not affect all businesses that grow produce; rather, the provisions of the rule would affect the subset of those businesses which grow covered produce with sales of total produce above the proposed $25,000 threshold (see subpart A, proposed §§ 112.1 – 112.6).

FDA proposed several size classifications of businesses in the PS PR. One of them is the *de minimis* threshold in total annual sales of produce ($25,000) below which farms would be exempt. The other size thresholds (small business, very small business, and all other farms) determine when farms would be required to comply with the provisions, if finalized. In addition, farms that meet certain criteria would be eligible for a qualified exemption and related modified requirements. Background information on the size thresholds of businesses to be excluded and covered by the PS PR is found in detail in Chapter 2.1, subpart A.

While information is available on the size of farms, the data do not identify the location of farms of specific sizes. As such, it is not possible to identify regions where there may be more small and very small businesses, or farms that do not meet the *de minimis* threshold. Farm operations in general often affect resources that are contained within larger, regional areas, such as water quality/quantity and air quality. Environmental resources and farm operations may be subject to both federal and state requirements.

Management decisions and impact analysis

FDA, in coordination with USDA, identified the reasonably foreseeable actions, or management decisions, that businesses potentially affected by any final rule might take in order to come into compliance with, or to potentially avoid being subject to, the alternatives under consideration for inclusion in any final rule. Management decisions were considered reasonably foreseeable if they were in compliance with existing laws and regulations, if they would allow for compliance with the alternatives being considered, if the technology to make such decisions is currently available or is in development, and if such decisions have been considered for the stated purpose. Management decisions that would only be suitable options for some covered produce were included, even if not a viable option for all covered produce. In response to the 2013 proposed rule and the supplemental proposed rule, we received numerous comments, including from industry, some of which provided information on the steps that covered farms would need to take to be in compliance with the rule, if finalized as proposed. FDA has completed its review of all comments received. Management decisions that were expressly stated or implied in these comments were considered in this EIS. We expect that farms would use one or a combination of these measures depending upon their individual conditions. These management decisions formulate the basis upon which FDA assessed potential environmental impacts in Chapter 4 of the EIS. We further received comment on the Draft EIS regarding the management decisions, including the likelihood of their occurrence and some suggestions for us to assess additional potential management decisions. We have considered these comments. As explained in more detail in Chapter 2.2 and Appendix E, we consider the management decisions proposed by commenters in response to the Draft EIS to be not reasonably foreseeable or to not meet the agency's stated purpose and need.

ES.4 Alternatives evaluated in the EIS

We evaluated in the EIS the environmental (including human) and related socioeconomic impacts for those provisions of the PS PR that FDA has determined may significantly affect the quality of the human environment (identified in Section E.3 as "potentially significant provisions"), the determination of which was based on comments from the public and other federal agencies prior to and during the EIS scoping period, and alternatives to those provisions. After publication of the Draft EIS, some commenters submitted additional alternatives for us to consider. Based on its consideration of public comments, we did not add any new alternatives or potentially significant provisions for detailed analysis. However, we added a new subchapter to Chapter 2.2 that addresses potential alternatives from commenters that were eliminated from further review. This new subchapter, along with our comment response as provided in Appendix E, explains our rationale for eliminating these commenter-suggested alternatives from further review.

In addition to alternatives for potentially significant provisions, we evaluated in the EIS the No Action Alternative, which is made up of baseline agricultural practices, regulations, and industry programs, as well as background environmental conditions discussed in Chapter 3 of the Final EIS. By doing so, FDA assessed the current, ongoing environmental impacts related to the growing, harvesting, packing, and holding (*i.e.*, the No Action Alternative) of what would otherwise be "covered produce" in the PS PR, if FDA were not to finalize the PS PR.

Chapter 2.1 of the Final EIS presents a detailed description of the proposed alternatives, including alternatives that were modified or removed entirely after the scoping period for the EIS closed. The alternatives provided in this executive summary represent those that were carried forward for analysis as we prepared the Final EIS.

Potentially significant provisions and their alternatives for analysis in the EIS

(Subpart E) Standards directed to agricultural water (proposed §§ 112.41 to 112.50)

Additional information on subpart E, including baseline agricultural conditions, is found in Chapter 2.1 of the Final EIS. FDA evaluated the following four alternatives related to subpart E:

I. As proposed, *i.e.*, an STV not exceeding 410 CFU of generic *E. coli* per 100 ml of water and a GM not exceeding 126 CFU of generic E. coli per 100 ml of water, along with options to achieve the standard by applying either a time interval between last irrigation and harvest using a microbial die-off rate of 0.5 log per day and/or a time interval between harvest and end of storage using an appropriate microbial die-off or removal rates, including during activities such as commercial washing.

   Management decisions associated with this alternative include to use chemical treatment, change the irrigation mechanism, change the water source, stop growing covered produce, or to add a mechanism to account for microbial die-off.

II. A microbial quality standard of no more than 235 CFU (or MPN, as appropriate) generic *E. coli* per 100 ml for any single sample or a rolling GM (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 ml of water, as originally proposed in the 2013 proposed rule.

Management decisions associated with this alternative include to use chemical treatment, change the irrigation mechanism, change the water source, or to stop growing covered produce.

III. As proposed (*i.e.*, Alternative I), but with an additional criterion establishing a maximum generic *E. coli* threshold.

Management decisions associated with this alternative include to use chemical treatment, change the irrigation mechanism, change the water source, or to stop growing covered produce.

IV. For Alternatives I, II, and III, FDA considered the environmental impacts of an interpretation of the definition of "direct water application method" that assumes that agricultural water applied using direct water application methods would not be in direct contact with covered crops unless the harvestable or harvested portion of the crop was above the soil surface to some extent, *e.g.*, carrots, where a portion of the vegetable and the edible greens would be above the surface. Conversely, Alternative IV considers an interpretation of the definition of "direct water application method" that would include root crops that are irrigated using low-flow methods, such as drip irrigation where contact is intended to, or likely to, occur with the harvestable or harvested portion of the crop below the soil. This essentially creates 3 subalternatives:

Alternative IV-a: An STV not exceeding 410 CFU of generic *E. coli* per 100 ml of water and a GM not exceeding 126 CFU of generic *E. coli* per 100 ml of water, along with options to achieve the standard by applying either a time interval between last irrigation and harvest using a microbial die-off rate of 0.5 log per day and/or a time interval between harvest and end of storage using an appropriate microbial die-off or removal rates, including during activities such as commercial washing. Alternative IV-a applies Alternative I to all covered produce including root crops that use low-flow irrigation methods, *e.g.*, drip irrigation. Alternative IV-a represents the alternative that would best fulfill FDA's statutory mission and responsibilities related to the microbial quality standard for agricultural water when agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method.

Alternative IV-b: When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method the grower must test the quality of water in accordance with one of the appropriate analytical methods in subpart N (§§ 112.151 – 112.152). If there is more than 235 CFU (or MPN, as appropriate) generic *E. coli* per 100 ml for any single sample or a GM (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 ml of water, the grower must immediately discontinue use of that source of agricultural water and/or its distribution system for the

uses described [in § 112.44(c)]. Alternative IV-b applies Alternative II to all covered produce including root crops that use low-flow irrigation methods, *e.g.*, drip irrigation.

Alternative IV-c: This alternative incorporates the provision, as proposed under Alternative I and, therefore, Alternative IV-a, but with an additional criterion establishing a maximum generic *E. coli* threshold. In the supplemental proposed rule, FDA requested public comment on any potential maximum threshold. Alternative IV-c applies Alternative III to all covered produce including root crops that use low-flow irrigation methods, *e.g.*, drip irrigation.

Management decisions associated with these subalternatives include to use chemical treatment, change the irrigation mechanism, change the water source, stop growing covered produce, or to add a mechanism to account for microbial die-off.

(Subpart F) Standards directed to biological soil amendments of animal origin and human waste (proposed §§ 112.51 to 112.60)

Additional information on subpart F, including baseline agricultural conditions, is found in Chapter 2.1 of the Final EIS. FDA considered alternatives for untreated (raw) BSAs of animal origin and treated (composted or processed) BSAs of animal origin. FDA evaluated the following alternatives in the Final EIS related to untreated BSAs of animal origin:

Untreated BSAs of animal origin

FDA considered comments that it received on the PS PR and during the EIS scoping period with respect to the 9 month minimum application interval (Alternative I) for use of raw manure in proposed § 112.56(a)(1)(i). As a result, FDA proposed to remove the minimum application interval in proposed § 112.56(a)(1)(i) and defer its decision on an appropriate minimum application interval until it pursues certain actions, including a robust research agenda, risk assessment, and efforts to support compost infrastructure development, in concert with USDA and other stakeholders. With respect to the Final EIS, FDA determined it is still appropriate to evaluate the potential environmental impacts from implementing proposed § 112.56(a)(1)(i) (as well as alternatives identified in this Chapter), as FDA does intend to finalize this provision to establish an appropriate minimum application interval at a future point in time.

FDA evaluated the following five alternatives related to untreated BSAs of animal origin:

I. If the BSA of animal origin is untreated and is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, then the minimum application interval (*i.e.*, time between application and harvest) must be nine months (§ 112.56(a)(1)(i), as originally proposed in the 2013 proposed rule).

Management decisions associated with this alternative include to switch to treated material, use BSAs of non-animal origin, use chemical fertilizers, observe the requisite waiting period (wait 9 months), stop growing covered produce, or to change the application method.

II. If the BSA of animal origin is untreated and is applied in a manner that does not contact covered produce during application and minimizes the potential for contact after application, then the minimum application interval (*i.e.*, time between application and harvest) must be zero days. As noted above, FDA removed the originally proposed 9 month minimum application interval and deferred decision on an appropriate time interval until FDA pursues certain actions. Therefore, an alternative that would best meet the statutory mission and responsibilities has not been identified. For the purpose of determining environmental impacts, in the absence of a decision on the alternative which would fulfill the statutory mission, the impacts associated with the 0 day application interval were included with the aggregate environmental impacts under subpart A (see Chapter 4.7 of the Final EIS and Section ES.6 in this summary document).

Management decisions associated with this alternative include to switch to treated material, use BSAs of non-animal origin, use chemical fertilizers, observe the requisite waiting period (wait 0 days), stop growing covered produce, or to change the application method.

III. Application interval consistent with USDA organic regulations that specify application intervals for the use of raw manure as a soil amendment (*i.e.*, 90 days and 120 days before harvest) depending on whether the edible portion of the crop contacts the soil (as specified in 7 CFR 205.203(c)(1)).

Management decisions associated with this alternative include to switch to treated material, use BSAs of non-animal origin, use chemical fertilizers, observe the requisite waiting period (wait 90/120 days), stop growing covered produce, or to change the application method.

IV. If the BSA of animal origin is untreated and is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, then the minimum application interval (*i.e.*, time between application and harvest) must be six months.

Management decisions associated with this alternative include to switch to treated material, use BSAs of non-animal origin, use chemical fertilizers, observe the requisite waiting period (wait 6 months), stop growing covered produce, or to change the application method.

V. If the BSA of animal origin is untreated and is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, then the minimum application interval (*i.e.*, time between application and harvest) must be 12 months.

Management decisions associated with this alternative include to switch to treated material, use BSAs of non-animal origin, use chemical fertilizers, observe the requisite waiting period (wait 12 months), stop growing covered produce, or to change the application method.

Treated BSAs of animal origin

FDA evaluated the following three alternatives in the Final EIS related to treated BSAs of animal origin:

I. As amended, proposed § 112.56(a)(4)(i) would establish that if the BSA of animal origin is treated by a composting process in accordance with the requirements FDA proposed in § 112.54(c) to meet the microbial standard proposed in § 112.55(b), and is applied in a manner that minimizes the potential for contact with covered produce during and after application, then the minimum application interval (*i.e.*, time between application and harvest) is zero days. This alternative would best fulfill FDA's statutory mission and responsibilities, as proposed.

   Management decisions associated with this alternative include to use BSAs of non-animal origin or processed material, use chemical fertilizers, observe the requisite waiting period (wait 0 days), or to change the application method.

II. If the BSA of animal origin is treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b), then the BSA of animal origin must be applied in a manner that minimizes the potential for contact with covered produce during and after application, and then the minimum application interval is 45 days.

   Management decisions associated with this alternative include to use BSAs of non-animal origin or processed material, use chemical fertilizers, observe the requisite waiting period (wait 45 days), or to change the application method.

III. If the BSA of animal origin is treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b), then the BSA of animal origin must be applied in a manner that minimizes the potential for contact with covered produce during and after application, and then the minimum application interval is 90 days.

   Management decisions associated with this alternative include to use BSAs of non-animal origin or processed material, use chemical fertilizers, observe the requisite waiting period (wait 90 days), or to change the application method.

(Subpart I) Standards directed to domesticated and wild animals (proposed §§ 112.81 to 112.84)

Additional information on subpart I, including baseline agricultural conditions, is found in Chapter 2.1 of the EIS. FDA considered alternatives for domestic animal grazing and wild animal intrusion. FDA evaluated the following three alternatives in the Final EIS related to domestic animal grazing:

Domesticated animal grazing

I. At a minimum, if animals are allowed to graze or are used as working animals in fields where covered produce is grown, and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, the grower must take the following measures: (a) An adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed to ensure the safety of the harvested crop; and (b) If working animals are used in a growing area where a crop has been planted, measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce. This alternative would best fulfill FDA's statutory mission and responsibilities, as proposed.

   In addition, proposed § 112.84 would explicitly state that proposed part 112 does not authorize or require covered farms to take actions that would constitute the "taking" of threatened or endangered species in violation of the ESA, require growers to take measures to exclude animals from outdoor growing areas, or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. See the Chapter 4 subsection for *Resource components not included for review in the EIS*.

   Management decisions associated with this alternative include to construct fencing or to observe an adequate waiting period.

II. If animals are allowed to graze or are used as working animals in fields where covered produce is grown and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, the grower must employ a minimum waiting period of 9 months between the time grazing or working animals are present in areas where covered produce is grown and the time such produce is harvested from such growing areas, and measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce.

   This alternative is consistent with the provisions for the use of raw (untreated) manure as a BSA of animal origin, described in § 112.56(a)(1)(i) as it was proposed in the 2013 proposed rule. FDA's provision regarding the protection of habitat and species protected under the ESA in proposed § 112.84 would be carried forward to this alternative.

   Management decisions associated with this alternative include to construct fencing or to observe an adequate waiting period (wait 9 months).

III. If animals are allowed to graze or are used as working animals in fields where covered produce is grown, and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, the grower must employ a minimum waiting period of 90 days and 120 days before harvest, depending upon whether the edible portion of the crop contacts the soil (as specified in 7 CFR 205.203(c)(1)).

FDA's provision regarding the protection of habitat and species protected under the ESA in proposed § 112.84 would be carried forward to this alternative.

Management decisions associated with this alternative include to construct fencing or to observe an adequate waiting period (wait 90/120 days).

Wild animal intrusion

FDA evaluated the following two alternatives related to wild animal intrusion in the Final EIS:

I. As proposed, if under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce, the grower must monitor those areas that are used for a covered activity for evidence of animal intrusion: (1) as needed during the growing season based on (i) the covered produce and (ii) the grower's observations and experience; and (2) immediately prior to harvest.

If animal intrusion, as made evident by observation of significant quantities of animals, animal excreta or crop destruction via grazing occurs, the grower must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112 (proposed § 112.83(a) and (b)).[3]

Under this alternative, § 112.84 would also provide that nothing in this regulation authorizes the "taking" of threatened or endangered species as that term is defined by the Endangered Species Act (16 U.S.C. 1531–1544) (*i.e.*, to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), in violation of the Endangered Species Act. This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

This alternative would best fulfill FDA's statutory mission and responsibilities.

[3] Prior to the publication of the 2013 proposed rule, there were a few instances in which a foodborne illness outbreak resulted in growers taking extreme measures to exclude wildlife from their crops that resulted in substantial environmental impacts to wetland habitat. Upon the publication of the 2013 proposed rule, some members of industry expressed concern of a repeat of this or similar action taken on a nationwide scale. FDA, in the supplemental proposed rule, added provision § 112.84, which directly addresses actions related to the authority of the Endangered Species Act (16 U.S.C. 1531–1544). Therefore, this regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

Management decisions associated with this alternative include to not harvest all or part of the produce field, or to take measures to exclude wildlife (*e.g.*, fencing, trapping, hunting, poisoning).

II. If there is a reasonable probability that animal intrusion will contaminate covered produce, under this alternative FDA would require that the grower monitor these areas as needed during the growing season, based on the covered produce being grown and the grower's observations and experiences (proposed § 112.83(a)(1)(i) and (ii)), and immediately prior to harvest (proposed § 112.83(a)(2)). If animal intrusion is reasonably likely to occur, the grower must take measures to exclude animals from fields where covered produce is grown.

In addition, proposed § 112.84 would explicitly state that proposed part 112 does not authorize or require covered farms to take actions that would constitute the "taking" of threatened or endangered species in violation of the ESA, although it would not include the statement that the measure does not require measures to exclude animals from outdoor growing areas, or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainageways.

Management decisions associated with this alternative include to not harvest all or part of the produce field, or to take measures to exclude wildlife (*e.g.*, fencing, trapping, hunting, poisoning).

(Subpart A) General Provisions (proposed § 112.1 – 112.6)

Additional information on subpart A is found in Chapter 2.1 of the EIS. FDA evaluated the following alternatives related to general provisions of the proposed rule in the Final EIS:

I. A farm or farm mixed-type facility with an average annual monetary value of produce (as defined in proposed 21 CFR 112.3(c)) sold during the previous 3-year period of more than $25,000 (on a rolling basis) is a "covered farm" subject to part 112, and a "covered farm" subject to this part must comply with all applicable requirements of this part when conducting a covered activity on "covered produce" (proposed 21 CFR 112.4, as amended by the supplemental proposed rule). This alternative would best fulfill FDA's statutory mission and responsibilities.

Management decisions associated with this alternative include to either to comply with the provisions of the rule, or to switch to a non-covered crop.

II. Farms with $50,000 or less of annual value of food sold would be excluded from coverage of the PS PR.

Management decisions associated with this alternative include to either to comply with the provisions of the rule, or to switch to a non-covered crop.

III. Farms with $100,000 or less of annual value of food sold would be excluded from coverage.

Management decisions associated with this alternative include to either to comply with the provisions of the rule, or to switch to a non-covered crop.

IV. Farms with $25,000 or less of annual value of "covered produce" sold would be excluded from coverage.

Management decisions associated with this alternative include to either comply with the provisions of the rule, or to switch to a non-covered crop.

Provisions and alternatives that were considered but dismissed from detailed analysis

FDA also proposed in the PS PR standards that are primarily administrative in nature, or that do not result in significant environmental impacts on the human environment. For purposes of the Final EIS, FDA considers how these standards would contribute to the review of the "Socioeconomics and Environmental Justice" resource component when combined with other alternatives as part of analysis of the (subpart A) general provisions (Chapter 4.7 of the EIS) and the overall cumulative impact analysis (Section ES.9 or Chapter 5 of the Final EIS). The proposed standards that are dismissed from detailed analysis include subparts C, D, K, L, M, N, O, P, Q, and R (discussed in greater detail in Chapter 2.2 of the Final EIS).

FDA considered a number of alternatives that were identified early in the scoping process and that did not meet the purpose and need of the proposed action, or that were not feasible for reasons associated with cost. These are potential alternatives that were eliminated from further review (discussed in greater detail in Chapter 2.2 of the Final EIS). In summary, the options or alternatives evaluated included (1) no new regulatory action, (2) exclude commodities not associated with outbreaks from some or all of the provisions of the rule, (3) require less-extensive standards, (4) apply a $10,000 limit to an average annual monetary value of "food" sold during the previous three-year period, (5) apply a $25,000 limit to an average annual monetary value of "food" as the threshold above which farms would be subject to the rule, and (6) with respect to standards directed to agricultural water, no detectible *E. coli* per 100 ml.

After publication of the Draft EIS, FDA further considered alternatives from commenters that were received on that document. While we did not add any new alternatives for detailed evaluation as a result of these comments on the Draft EIS, we did address the suggested alternatives in Chapter 2.2 of the Final EIS under the title, "*Potential alternatives from commenters that were eliminated from further review*." For example, commenters suggested that FDA consider removing the $25,000 threshold below which farms would be exempt from the rule, and to analyze the environmental impacts of developing a manure standard that accounts for application of biological soil amendments that fall between fresh manure and composted material, such as the application of aged manures. Our response to comments regarding suggested alternatives appears in Appendix E of the Final EIS.

ES.5 Affected Environment

As described in ES.3, the data and information concerning current farming practices for covered produce and the environmental impacts of such practices vary for each resource. FDA based the selection of resource components that we evaluated in the Final EIS on the information and feedback we received during the scoping period for the PS PR and the EIS, through consultation with other government agencies, and through public comments. As such, the resource components that we evaluated as part of its impact analysis include water resources; soils; waste generation, disposal, and resource use; biological and ecological resources; air quality; socioeconomics and environmental justice; and human health and safety.

ES.6 Environmental Impacts

Environmental consequences associated with implementing the potentially significant provisions of the rule, if finalized, are evaluated in Chapter 4 of the Final EIS. The analysis includes the alternatives for each potentially significant provision, and the possible management decisions that could be enacted by farm operators, screened against the purpose and need of the PS PR. A summary of the impacts associated with each alternative for the potentially significant provisions is presented below. The region letters presented in the following environmental impacts discussions refer to the regions presented in Figure ES-1.

Subpart E – Standards Directed to Agricultural Water

Alternative I: As Proposed. Geometric Mean ≤ 126 CFU generic *E. coli*/100ml and STV ≤ 410 CFU/100ml with added flexibility for microbial die-off and/or removal

- The flexibility in meeting the proposed water quality standard is likely to limit the need to use chemical treatment of a water source with poor water quality. It is also likely that a farmer might add a post-harvest mechanism to allow for added microbial die-off and/or removal.
- Disinfectants may be useful for reducing hazards that may cause foodborne illnesses; however, many of these disinfectants may form harmful byproducts. There is no EPA-registered pesticide that is approved for use for antimicrobial treatment of agricultural water used during the growing of crops. FDA cannot predict what the future actions of EPA, if any, will be with respect to registration of a pesticide to treat agricultural water, much less evaluate the unknown and speculative actions under NEPA. EPA-registered pesticide products are evaluated to determine potential environmental effects and potential impacts to human health specific to their use. We would expect environmental impacts from registered pesticide uses to not be significant considering how they are generally handled and applied according to label directions, which would be a reasonably foreseeable use (see Chapters 4.1 and 4.2). When used properly, the adverse effects of such chemicals are not persistent in the environment and water quality conditions would be expected to return to ambient conditions; wildlife, vegetation, and wetlands would be resilient to the effects of the chemicals at a regional or national level. In addition, a high number of growers in key growing regions, such as California, Arizona, and Florida (Regions C, D, and U), already participate in marketing agreements that have more

stringent numeric water quality standards than what FDA has proposed, and are already using water that would be in compliance with the proposed standard. In general, the existence of these marketing agreements, particularly in produce growing regions currently experiencing water impacts, minimizes the severity of potential impacts on resource components associated with a final rule, as the number of farms that may need to alter their current management practices is less than the total number of covered farms.

- It is not likely that a considerable amount of farmers will change the water source or cease growing covered produce because, among the regions that are potentially most affected (B, C, D, I, J, and U), many farmers have entered into marketing agreements that are the same as, or operate under more stringent water quality standards than those proposed in the PS PR. In addition, reactions and verbal comments from some industry and trade groups that FDA received on the supplemental proposed rule suggest that the new proposed provisions for microbial die-off and/or removal to achieve the proposed microbial quality standard considerably limit the perceived need to change water source in order to comply with Alternative I (and similarly Alternatives IV-a, III, and IV-c), compared to Alternative II or IV-b. Any action that may lead to increases in groundwater drawdown would be considered a significant environmental impact. Regions that may be most impacted in terms of potential land subsidence, including any additive effects by switching to groundwater sources, include the regions that already experience the highest groundwater withdrawals; these are regions B, C, D, I, J, and U. Such effects related to groundwater drawdown may further be experienced transboundary in the Northeastern and Northcentral reaches of Mexico, corresponding to groundwater withdrawals from aquifers in regions D, I, and J in the United States.
- Overall, there would be an expected added public health benefit from an estimated 522,083 foodborne illnesses prevented (FDA, 2013b) from the standard alone.
- Air quality emissions would not be expected to result in adverse effects to human health at a regional or national level.

Alternative II: GM of no more than 126 CFU (or MPN)/100 mL and a single sample maximum of 235 CFU (or MPN) generic *E. coli* /100 ml single sample or a Geometric Mean of no more than 126 CFU (or MPN)/100 ml

The adverse environmental impacts and beneficial public health benefits that may apply under Alternative I would also apply under this alternative; however, due to the more stringent requirements for this alternative, the following environmental impacts may occur in addition to those discussed under Alternative I:

- Under this alternative, switching water source is expected to be the preferred management decision. As compared to Alternatives I, IV-a, III, or IV-c, this alternative would not have the added flexibility for microbial die-off and/or removal; therefore, farmers are more likely to decide to switch water sources, particularly away from surface waters to a cleaner source. If the cleanest available source is groundwater, then existing significant adverse conditions (*i.e.*, water drawdown, potential subsidence, and the related continued degradation of water quality) may continue to be exacerbated but to a greater degree than Alternative I, because the water quality requirements would be more stringent under this alternative and more farms are potentially likely to switch to the groundwater source in numbers that may considerably influence groundwater sources. These impacts are expected to be limited to certain regions and are not

expected to be widespread. The regions that may be most affected are B, C, D, I, J, and U, as well as areas in the northeastern and northcentral reaches of Mexico that share an aquifer with region D, I, or J. These regions may also experience irreversible effects to soils. Therefore, these impacts under Alternative II related to lowering the water table, deteriorating water quality, and land subsidence are considered significant adverse.

- Native American Tribes may be disproportionately impacted as groundwater drawdown could have potential environmental impacts including socioeconomic impacts related to access to water on reservations, particularly in regions B and J. Such impacts would be considered significant adverse if there is a reduction in a Tribe's access to water.
- Treating any water source to remove harmful pathogens would have an added public health benefit by reducing the potential for foodborne illnesses.
- There would also be greater potential for the use of chemical treatments to bring water into compliance under this alternative relative to Alternatives I, IV-a, III, or IV-c. Consequently, we would anticipate that this alternative would have more adverse environmental consequences than Alternatives I, IV-a, III, or IV-c. As previously stated, all pesticides must be registered by EPA and must be found to not generally cause unreasonable adverse effects on the environment when properly used. When used properly, the adverse effects of such chemicals are not persistent in the environment and water quality conditions would be expected to return to ambient conditions; wildlife, vegetation, and wetlands would be resilient to the effects of the chemicals at a regional or national level. However, without the added flexibility for die-off that is afforded under Alternatives I, IV-a, III, or IV-c, regions that potentially require a higher level of chemical treatment include A, B, C, L, R, T, and U. Generally, long-term, sustained treatment of water sources may result in adverse, but not significant impacts to water quality, and may also result in non-significant, adverse long-term effects to biological/ecological resources and air quality from chemical treatments. Even under these circumstances, chemicals are not expected to persist and water quality conditions would be expected to return to ambient conditions; wildlife, vegetation, and wetlands would be resilient to the effects of the chemicals at a regional or national level.
- The risk of adverse impacts to human health relating to the increased use of chemicals would not be expected to be significant and may be limited through adherence to labeling requirements, as the FIFRA registration process considers risk to human health and establishes handling processes that are appropriate to minimize such risks. The possibility of potential impacts from THMs to be formed may occur in regions that may require the highest treatments (see above). To the extent a future EPA-registered pesticide includes a chemical that results in the formation of THMs, these substances are not expected to be formed at levels that may endanger public health with properly application (see Chapter 4.2). Overall reductions in foodborne illnesses are expected to be comparable under Alternative I, IV-a, III, and IV-c.
- Air quality emissions would not be expected to result in adverse effects to human health at a regional or national level.

Alternative III: As proposed (*i.e.*, Alternative I), with an additional criterion establishing a maximum generic *E. coli* threshold

- Compared to Alternatives I and IV-a, there is a slightly higher likelihood that more farmers may select to chemically treat water sources or switch water sources altogether because there may

be circumstances when the pathogen level would exceed the established threshold and when steps allowing for die-off would not be sufficient to be in compliance with the rule. However, the reduced water testing and the less stringent standard means that fewer farms would be expected to make these management decisions as compared to Alternatives II and IV-b.

- The beneficial environmental impacts to health would likely be higher than Alternatives I and IV-a, and lower than Alternatives II and IV-b.
- Similar to what is addressed above, the use of pesticides is found to not generally cause significant adverse effects to the environment, so long as such products are handled in accordance with their labeling requirements (see Chapter 4.2). We would expect adverse impacts to human health related to handling such substances and treating poor water quality to be not significant, but such future registered uses, if any, are unknown and simply speculative at this time.
- As compared to Alternative I, establishing a maximum threshold for generic *E. coli* may cause some growers in a region where the water quality is poorest to potentially shift from growing covered produce, but not to the degree that may occur under Alternatives II or IV-b. These potential shifts are limited by the fact that existing marketing agreements in the most impacted regions already operate with more stringent numeric water quality standards, and also account for more than 80 percent of the produce that would be covered by the rule.

Alternative IV: Alternatives for direct water application method

- Similar to Alternative I, under Alternative IV-a mechanism(s) to account for microbial die-off and/or removal is expected to be the preferred management decision. Due to the added flexibility associated with this alternative, long-term chemical treatment of agricultural water would not be necessary. Therefore, under Alternative IV-a, switching water source and ceasing to grow covered produce are not expected to be preferred management decisions. The impacts under Alternative IV-a would be substantially similar to those identified under Alternative I, and slightly fewer impacts as compared to Alternatives III and IV-c. Environmental impacts are expected to be significantly less than those identified under Alternatives II and IV-b.
- Under Alternative IV-b, there may be a greater potential to switch to a cleaner water source or to treat the water source in order to meet the microbial water quality standard as compared to Alternatives I, IV-a, III, or IV-c. The impact analysis under Alternative IV-b would be substantially similar to those identified under Alternative II, therefore, impacts are expected to be greater under this alternative as compared to Alternatives I, IV-a, III, or IV-c.
- Under Alternative IV-c, there is a somewhat greater potential to switch to a cleaner water source or to treat the water source in order to meet the microbial water quality standard as compared to Alternatives I and IV-a, but less of a potential to select these management decisions as compared to Alternatives II and IV-b. The impact analysis under Alternative IV-c would be substantially similar to those identified under Alternative III; therefore, impacts are expected to be greater under this alternative as compared to Alternatives I and IV-a.

Subpart F: Standards directed to BSAs of animal origin and human waste

Untreated BSAs of animal origin

Alternative I: As previously proposed (decision deferred). Untreated BSAs of animal origin must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 9 months.

- Covered produce growers located in regions A, B, C, D, J, M, L, P, S, U and V are located in proximity to livestock and/or poultry operations, which are a source of available BSAs of animal origin.
- Given the long interval between application and harvest, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period.
- If farmers switch to treated manure and the nutrient availability of the treated manures is unknown or difficult to predict, then regular testing would be required to allow farmers to properly apply manure to meet agronomic needs and environmental goals. With proper management, no adverse impact to soil health will occur. In addition, treatment will require additional storage time, which presents more opportunity for partially processed manure to impact surface and groundwater; however, adherence to common best management practices may reduce these impacts. If the storage of manure occurs at a facility that operates under an NPDES permit, as long as the facility is managed in accordance with permit requirements, potential adverse impacts are anticipated to further be limited (we recognize that not all of these farms will have a requirement for NPDES permits).
- The production and transport of chemical fertilizers may have an adverse but not significant impact on energy use and air quality because the resource use is not expected to change substantially as compared to current baseline conditions and, therefore, the impacts to public health from air emissions would not rise to a significant impact at a regional or national level (see Chapter 2.1 subpart F, Chapter 3.4, and Chapter 4.3 in the Final EIS).
- Given the small number of farms that use untreated BSAs of animal origin (estimated at 821 covered farms, or 2.3 percent of covered farms nationally) that could possibly switch to chemical fertilizers, the overall impacts to the environment would not rise to a significant impact at a regional or national level. The proper use and handling of chemical fertilizers, and adherence to manufacturer's recommendations and use of chemical fertilizers according to label directions, which is reasonably foreseeable, would result in an expected return of water quality to ambient conditions.
- The proper use and handling of chemical fertilizers, and adherence to manufacturer's recommendations for using personal protective equipment, are reasonably foreseeable uses of these products; therefore, we do not expect significant adverse effects to human health from their use.
- The use of chemical fertilizers could cause moderate, but not significant, adverse environmental impacts to soils. Current trends show that other practices such as green manuring, no-till practices, and use of cover crops are growing in popularity. To the extent that these practices

are adopted by the agricultural industry, they would help to control the magnitude of adverse environmental impacts.

- If growers choose to comply with the 9 month interval instead of changing the soil amendment type or application method, a minimal (not significant) impact is expected to result from the growing regime or from a reduction in the number of crops a farmer may harvest due to the small number of farms nationwide that would be impacted. There may be some reduction in farm income if farms need to set aside land or build structures to store the untreated BSAs of animal origin. The amount of produce may be reduced due to a reduced number of harvests per year based on a 9 month waiting period. This may cause an increase in the price of certain produce if supply is reduced and demand is high. However, we expect that any such increase would be prevented by other growers (*i.e.*, regionally, locally, and internationally) filling any gaps in supply. Similar effects would be expected if growers stop growing covered produce, and regional produce commodity prices may increase resulting from a decrease in produce grown in any particular region; however, demand for a certain produce commodity may eventually be met by other growers in the region, growers in other regions (commodity and environment specific), or international suppliers.
- According to FDA estimates (2013b, 2014b), the number of illnesses that would be prevented from finalizing a BSAs of animal origin provision is 244,917; of these illnesses prevented, 156,299 would result from the 9 month application interval, with a total health cost benefit of an estimated $14.46 million.

Alternative II: Untreated BSAs of animal origin must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 0 days.

- This alternative is similar to the existing condition but with the need to apply in a manner that does not contact covered produce during application.
- If a farmer is allowed to use an interval of 0 days between the application of raw manure and harvest, there is no regulatory need to treat raw manure. Therefore, changes in the type of soil amendment used or crop grown are not anticipated as a result of this management decision. Complying with the 0 day waiting period could require a change in application method for those farms that currently surface treat BSAs of animal origin, as they would need to ensure that it does not contact the covered produce during application.
- Changing the application method to prevent the contact of raw manure with a covered produce crop will potentially require the acquisition of additional equipment. This will require the outlay of funds for the purchase of new equipment and its ongoing maintenance. However, we do not expect a loss of income or employment to result at a significant level on a regional or national level due to the small number of farms potentially affected.
- Beneficial environmental impacts to human health would occur as a result of implementing this alternative, but the benefits would be minimal (not as effective) as compared to the Alternative I.

Alternative III: Application interval consistent with USDA organic regulations for the use of raw manure as a soil amendment, *i.e.*, 90 days and 120 days before harvest, depending on whether the edible portion of the crop contacts the soil (as specified in 7 CFR 205.203(c)(1)).

- With the exception of the short season crops listed in Table 3.4-5 (see Chapter 3.4 in the Final EIS) with growing to harvest cycles of 45 days or less, most crops have a growing cycle of about three to four months. For such crops, no changes would be required to management practices in order to comply with this application interval. Additionally, farmers currently in the USDA organic program have adapted their growing practices to be in compliance with this alternative. If a certified organic grower chooses to treat raw manure, the grower will be limited in the choices for treatment in order to maintain its organic status. The small percentage of covered farms which utilize untreated BSAs, as well as the high likelihood that such farms are certified organic growers, indicates that few farms would need to change practices in order to comply with this application interval. As a result, no significant impacts are associated with any management decision under this alternative.
- Other farms that may be associated with marketing agreements that have more stringent application intervals may continue to observe their established standards if they are more stringent than what FDA proposes.
- Some additional public health benefits may occur over the present conditions for farms that may be using a zero day application rate. The switch to a longer application rate to harvest interval may result in more (unquantified) foodborne illnesses prevented over Alternative II, but still fewer than what is estimated for Alternative I.

Alternative IV: Untreated BSAs of animal origin must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 6 months

- As with Alternative I, given the long interval between application and harvest, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period.
- We would expect proper nutrient management, *e.g.*, proper storage, nutrient management plans, careful selection of application methods, and use of chemical fertilizers according to label directions, will limit any adverse impact to a level that is not significant. With proper use of chemical fertilizers, water quality would be expected to return to ambient conditions.
- If farmers switch to treated manure and the nutrient availability of the treated manures is unknown or difficult to predict, then regular testing would be required. While the current factors may be adequate for general estimating of typical manure nutrient availability, more precise estimates of both nitrogen and phosphorus availability based on compositional analyses are needed to guide producers toward economical and environmentally benign application rates when using treated manures. With proper management, no significant adverse impact to soil health would occur.
- The use of chemical fertilizers could cause moderate, but not significant, adverse environmental impacts to soils. Current trends show that other practices such as green manuring, no-till practices, and use of cover crops are growing in popularity. To the extent that these practices are adopted by the agricultural industry, they would help to control the magnitude of the adverse environmental impacts. The production and transport of chemical fertilizers may have an adverse but not significant impact on energy use and air quality because the resource use is not

expected to change substantially as compared to current baseline conditions; therefore, the impacts to public health from air emissions would not rise to a significant level at a regional or national level

- Changing the application method to prevent the contact of raw manure with a covered produce crop may require the acquisition of additional equipment, which would equate to a one-time outlay of funds for the purchase of new equipment and its ongoing maintenance. However, we do not expect a loss of income or employment to result at a significant level on a regional or national level due to the small number of farms potentially affected. Similar to Alternative I, if growers chose to switch to a non-covered crop, regional produce commodity prices may increase, resulting from a decrease in produce grown in any particular region; we consider such impacts unlikely, however, as demand for a certain produce commodity would likely be met by other growers in the region, growers in other regions (commodity and environment specific), or international suppliers.
- This alternative may result in improved public health benefits over Alternatives II and III but less than Alternatives I or V, due to the longer application-to-harvest interval.

Alternative V: Untreated BSAs of animal origin must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 12 months

- As with Alternatives I and IV, given the long interval between application and harvest, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period. Switching to treated material would reduce the interval between application of the treated manure and harvest to 0 days, rather than the interval of 12 months for the use of raw manure.
- Impacts under Alternative V would be substantially similar to those described under Alternatives I and IV.
- This alternative may result in improved public health benefits over all other alternatives due to the longer application-to-harvest interval. Several marketing agreements already observe a similar minimum application interval.

Treated BSAs of animal origin

Alternative I.: As proposed. Minimum application interval of 0 days.

- This alternative is similar to the current baseline conditions. No impacts would be associated with this alternative and corresponding management decisions. The use of chemical fertilizers in place of treated BSAs of animal origin as a nutrient source is unlikely to occur under this alternative because the alternative does not restrict the timing of the use of BSAs, but contains the requirement that the treated BSAs of animal origin be applied in a manner that does not contact covered produce.

Alternative II: Minimum application interval of 45 days.

- With the exception of the short season crops listed in Table 3.4-6 with growing to harvest cycles of 45 days or less, most crops have a growing cycle of about three to four months. Therefore, for most crops, an application interval of 45 days would not require any changes in the soil amendment type in order to comply with the requisite waiting period. Because this alternative is largely representative of the existing condition, no significant environmental impacts would be associated with this alternative and corresponding management decisions.

Alternative III: Minimum application interval of 90 days.

- As discussed under Alternative II, most crops have a growing cycle of about three to four months. Therefore, an application interval of 90 days would not require any changes in the soil amendment type in order to comply with the requisite waiting period. No significant environmental impacts would be associated with this alternative and corresponding management decisions.

Subpart I: Standards directed to domesticated and wild animals

Grazing

Alternative I.: Adequate waiting period.

- Given that only approximately 2,829 dual- or multi-purpose farms both raise livestock or poultry and grow produce (and some smaller subset of this number grows covered produce), the overall regional and nationwide potential environmental impacts from grazing operations would be minimal. This provision is expected to affect between 1.5 and 8 percent of growers of covered produce.
- Any measures taken to permanently exclude domestic animals (although not required by the rule) from covered produce would not have significant environmental impacts relative to a waiting period for harvesting covered produce. Although there may be some measures such as fencing (not required by the rule) that farmers without fencing may establish to exclude domesticated animals, any potential environmental impacts are not expected to be significant. Related impacts to fencing could include clearing a border around the farm field, thereby potentially removing vegetation. Reduced access to forage and cover for wildlife species due to the fencing or other exclusion measures may disrupt the existing wildlife corridors of transient terrestrial animal species, but few such disruptions are anticipated because exclusion measures could be ineffective to prevent wildlife from entering farm fields and because general impacts to wildlife habitat would be limited to the borders of the fields where such exclusion measures may be implemented.
- The application of chemicals such as herbicides to control vegetation around farm fields, and the application of insecticides/pesticides to control other pests could result in adverse effects to water quality. However, when applied in accordance with their labeling requirements, which would be a reasonably foreseeable use, the impacts are not expected to be significant, and water

quality conditions would be expected to recover to ambient conditions. The quantities of air emissions and GHGs related to fencing or other exclusion measures are not expected to result in public health concerns because there would be no measureable change to the air quality environment over existing conditions. In addition, all of these aforementioned impacts take into consideration the very small number of farms potentially affected by this provision where such impacts may occur.

- The more likely management decision would be to factor in the crop and region in which the crops are grown to allow for consideration of late growing seasons and other factors when determining when to remove the animal from the field at some time during the planting to harvest interval. Unlike Alternatives II and III, this alternative provides flexibility for farmers to make the decision on an appropriate time interval, based on the farm's operation.
- Because such dual-purpose operations are mostly anticipated to have confined grazing or other areas for livestock already (produce fields and livestock management are not typically compatible because most livestock, if allowed to graze in produce fields, would consume much of the commodity), removing the animal from fields where covered produce may be grown, relative to a planting/harvest interval, is not anticipated to result in adverse impacts (other than what is presently experienced) to either the produce field or to the field(s) to which the animal is confined.
- Any measure taken to reduce the hazard from pathogen transport to produce is expected to result in beneficial impacts to human health; however, relative to a permanent exclusionary measure, a management decision to include an adequate waiting period before using a field for growing covered produce may have less human health benefits (*i.e.*, in terms of foodborne illnesses prevented) compared to creating a barrier to animal entry and grazing entirely. A notable exception to human health benefits could be the use and handling of chemicals as part of a strategy to exclude domestic animals from farm fields. However, as discussed in Chapter 4.1, the proper use and handling of such chemicals, and adherence to manufacturer's recommendations for using personal protective equipment, are reasonably foreseeable uses of these products and we would not expect significant adverse effects to human health from these uses.

Alternative II: Waiting period of 9 months.

- As compared to Alternatives I and III, there are no substantially different impacts that can be estimated at a regional or national level; this alternative takes into consideration the very small number of farms to which this provision would apply.

Alternative III: Waiting period of 90/120 days.

- As compared to Alternatives I and II, there are no substantially different impacts that can be estimated at a regional or national level; this alternative takes into consideration the very small number of farms to which this provision would apply.

Animal Intrusion

Alternative I.: Evaluate whether produce can be harvested safely.

- Under Alternative I, there would be no significant adverse impacts expected with respect to any specific resource component.
- Evaluating whether produce can be harvested safely and, as appropriate, not harvesting a field or part of a field that is reasonably believed to be contaminated from wildlife intrusion would have no environmental impacts to water resources, waste generation, disposal, and resource use, and air quality. There may be minimal, non-significant beneficial environmental impacts observed to wildlife species as a result of added short-term cover and forage area from not harvesting part of the field and to soils from nutrients and carbon that would be reincorporated into the soils and lengthened surface cover to maintain or improve soil health.
- In terms of reducing pathogens, impacts are expected to be beneficial. Requiring the farmer to evaluate whether or not covered produce should be harvested based on the likelihood of being contaminated by animal intrusion would reduce potential pathogenic exposure to consumers. If the farmer does not harvest the field or part of the field in order to avoid harvesting contaminated covered produce, there would be a moderate beneficial impact on human health and safety.
- Chemicals used in exclusion measures may result in adverse effects to human health for the farmworkers that may be applying the chemical treatments. However, with the proper use and handling of such chemicals, in accordance with the manufacturer's labeling requirements (including heeding recommendations or requirements for personal protective equipment such as chemical-resistant gloves), we do not expect these impacts to human health and safety to be significant.

Alternative II: Measures to exclude wildlife.

- As compared to Alternative I, environmental impacts would be greater.
- Measures to exclude wildlife (including measures to clear land to facilitate monitoring) may involve the use of herbicides, rodenticides, or other materials that may have short-term toxic effects to water resources, biological resources and ecosystems directly adjacent to the farm, and soils. These impacts may be minimized through proper use and handling in accordance with labeling requirements, as EPA, in cooperation with states, carefully regulates these chemicals to ensure they do not pose an unreasonable risk to human health or the environment. EPA requires manufacturers to conduct extensive testing in order to identify any potential risks, and the agency carefully reviews these data provided by manufacturers before the product may be registered for use. Therefore, we do not anticipate significant adverse effects associated with these products. The overall environmental impacts would be limited because the chemical components generally quickly dissipate or decompose, and do not persist in the environment. Measures that may be employed to reduce any other potential adverse effects that may otherwise be significant include preparing pest management plans.
- Hunting, trapping, and animal poisoning are other methods that are sometimes used to manage wildlife species on or adjacent to farm fields. Hunting and trapping are often accomplished in accordance with state or county permit requirements and in accordance with state wildlife regulations, which factor in species population levels before determining the number of

licenses/permits that can be issued without adversely impacting species survivability (USFWS, 2000). For example, deer damage permits may be available to farmers that have experienced crop damage as a result of deer entering their production fields. These permits allow for the shooting of a specified number of deer during a certain period, usually outside of the normal hunting season.

- Under this alternative, proposed § 112.84 would also state that Part 112 does not require covered farms to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.
- Costs under Alternative II would be higher than what would be expected under Alternative I.
- In terms of reducing pathogens, impacts are expected to be beneficial. Chemicals used in exclusion measures may result in adverse effects to human health for the farmworkers that may be applying the chemical treatments. However, with the proper use and handling of such chemicals, in accordance with the manufacturer's labeling requirements (including heeding recommendations or requirements for personal protective equipment such as chemical-resistant gloves), we do not expect these impacts to human health and safety to be significant.

Subpart A: General Provisions (Scope of Coverage of the Proposed Rule); includes impacts related to the aggregate impacts of each proposed standard assessed together

We conducted a comparison of aggregate environmental impacts under subpart A by considering the alternatives that would best fulfill FDA's statutory mission and responsibilities. For subpart E, the added flexibility to meet a generic *E. coli* water quality standard for all covered produce (including root crops), is best represented by Alternative IV-a. For subpart F untreated BSAs of animal origin, where FDA has signaled its intent to defer finalization of a standard, the zero days standard, or Alternative II, is used for purposes of this evaluation. Subpart F (treated BSAs of animal origin) is best represented by Alternative I. Subpart I (Grazing), Alternative I, observing an adequate waiting period is the alternative that would best fulfill FDA's statutory mission and responsibilities, as growers would be able to factor in the crop and region in which the crops are grown to allow for consideration of late growing seasons and other factors when determining when to remove the animal from the field at some time during the planting to harvest interval. For subpart I (Animal Intrusion), Alternative I would best fulfill FDA's statutory mission and responsibilities. Requiring the farmer to evaluate whether or not covered produce should be harvested based on the likelihood of being contaminated by animal intrusion would reduce potential pathogenic exposure to consumers, as compared to exclusion measures such as fencing, which may be an ineffective means of keeping wildlife from the farm field.

Water Resources–

- Significant current and ongoing adverse impacts such as reduced water availability, water-table declines, soil subsidence and increased costs for finding and maintaining access to water, resulting from groundwater withdrawals are presently experienced in regions B, C, D, I, J, and U. These impacts represent the current condition, absent of any final rule, and are the result of many factors that include agricultural practices nationwide, development, and other factors unrelated to FDA's proposed action. Any action (personal, federal, state, local, etc.) in these regions that would cause a farmer or any entity to draw from groundwater instead of surface

water could exacerbate the current environmental conditions, as well as conditions in the northeastern and northcentral reaches of Mexico that share an aquifer with region D, I, or J in the United States. Under such conditions, individuals on Native American reservations in regions B and C may be disproportionately adversely impacted as a result of continued groundwater drawdown. We consider impacts from actions that result in groundwater drawdown to be significant in regions where current conditions for groundwater depletion have significant environmental impacts. Such impacts are considered under the cumulative impacts section, Chapter 5.

- The flexibility in meeting the proposed water quality standard is likely to limit the need to use chemical treatment of a water source with poor water quality. It is also likely that a farmer might add a post-harvest mechanism to allow for added microbial die-off or removal in lieu of treating the water source.
- It is not likely that a considerable amount of farmers will change the water source or cease growing covered produce because, among the regions that are potentially most affected (B, C, D, I, J, and U), many farmers have entered into marketing agreements that establish numeric standards that are the same as, or are more stringent than, those proposed in the PS PR. In general, the existence of these marketing agreements, particularly in produce growing regions currently experiencing water impacts, minimizes the severity of potential impacts on resource components. In addition, reactions and verbal comments from some industry and trade groups that FDA received on the supplemental proposed rule suggest that the new proposed provisions for microbial die-off and removal to achieve the proposed microbial quality standard considerably reduce the perceived need to change water source in order to comply with Alternative IV-a. Any action that may lead to increases in groundwater drawdown would be considered a significant environmental impact. Regions that may be most impacted in terms of potential land subsidence, including any additive effects by switching to groundwater sources, include the regions that already experience the highest groundwater withdrawals. These are regions B, C, D, I, J, and U, as well as areas in the northeastern and northcentral reaches of Mexico that share an aquifer with region D, I, or J in the United States.
- The majority of the 285 covered sprouting operations draw from municipal water already. Only minimal adverse, local and not significant impacts may occur from water treatment effluent, and no nationwide or regional impacts are anticipated to water availability from those few operations that may connect to municipal water supplies.
- With respect to water quality and impacts considered under subpart F (untreated or treated), if a farmer is permitted to use an application interval of 0 days between the application of untreated or treated manure and harvest, there would be no substantial change from the baseline condition that would result in significant impacts to water quality or availability.

Biological and Ecological Resources–

- Adverse effects to biological and ecological resources relevant to groundwater drawdown are not expected (discussed above). A high number of growers in key growing regions, such as California, Arizona, and Florida (regions C, D, and U), already participate in marketing agreements that have more stringent numeric water quality standards than what FDA has proposed, and are already using water that would be in compliance with the proposed standard.
- With respect to subpart I (grazing) the more likely management decision would be to factor in the crop and region in which the crops are grown to allow for consideration of late growing

seasons and other factors when determining when to remove the animal from the field at some time during the planting to harvest interval, which provides flexibility for farmers to make the decision on an appropriate time interval, based on the farm's operation. Because such dual-purpose operations are mostly anticipated to have confined grazing or other areas for livestock already (livestock management does not occur in produce fields, as livestock, if allowed to graze in produce fields would consume much of the commodity), removing the animal from fields where covered produce may be grown, relative to a planting/harvest interval, is not anticipated to result in adverse impacts (other than what is presently experienced) to either the produce field or to the field(s) to which the animal is confined. With respect to subpart I (wildlife intrusion), the most likely management decision would be to evaluate whether produce can be harvested safely and, as appropriate, not harvest a field or part of a field that is reasonably believed to be contaminated from wildlife intrusion. We do not expect environmental impacts to water resources, waste generation, disposal, and resource use, and air quality associated with this management decision.

- For subpart I taken together, any measures, however unlikely, taken to exclude animals (including measures to clear land to facilitate monitoring) may involve the use of herbicides, rodenticides, or other materials that may have short-term toxic effects to water resources, biological resources and ecosystems directly adjacent to the farm, and soils. These impacts may be reduced through proper use and handling of such chemicals in accordance with labeling requirements, which would be a reasonably foreseeable use (see Final EIS Chapters 4.1 and 4.2). Assuming such methods are used, the usage of such chemicals are not expected to result in unreasonable impacts to the environment. Water quality conditions would be expected to recover to ambient conditions. Wildlife, vegetation, and wetlands would be resilient to the effects of the chemicals at a regional or national level. The quantities of air emissions and GHGs related to fencing or other exclusion measures are not expected to result in public health concerns because there would be no measureable change to the air quality environment over existing conditions. In addition, all of these aforementioned impacts take into consideration the very small number of farms potentially affected by this provision where such impacts may occur (at most 8 percent of covered farms). Measures that may be employed to reduce any other potential adverse effects that may otherwise be significant include preparing pest management plans. Additionally, proposed § 112.84 does not require covered farms to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. The alternative and more likely management decision that a farmer may make is to monitor their fields and evaluate whether produce can be harvested safely. As discussed above, any unharvested portions of the field may provide non-significant beneficial impacts to wildlife species as a result of added short-term cover and forage area.
- Hunting, trapping, and animal poisoning are other methods that are sometimes used to manage wildlife species at or adjacent to farm fields. Hunting and trapping are often accomplished in accordance with state or county permit requirements and in accordance with state wildlife regulations, which factor in species population levels before determining the number of licenses/permits that can be issued without adversely impacting the species survivability (USFWS, 2000). As discussed above, we do not expect any impacts from such methods to result in significant environmental impacts.

Soils–

- The added flexibility in meeting the proposed water quality standard is likely to reduce the need to change the water source; therefore, the aggregate impacts should not have direct effects on soils.
- However, as described in Chapter 3.3.3.4 of the Final EIS, the USGS has identified that more than 80 percent of the identified land subsidence in the nation is a consequence of groundwater exploitation. In many areas of arid western regions and in more humid areas underlain by soluble rocks such as limestone, gypsum, or salt, land subsidence is an often overlooked environmental consequence of land- and water-use practices. Figures 3.1-23 and 3.1-24 show the extent of excessive groundwater pumpage of aquifer systems throughout the U.S (see Final EIS Chapter 3.3.3.4), which correlate to areas where land subsidence is most likely to occur. Actions that would increase reliance on groundwater would potentially also impact soils. An impact on soils resulting from groundwater drawdown may result in impacts that are in addition to, but related to, irreversible compaction or subsidence, such as reduced ability to partition water for groundwater recharge and for use by plants and soil organisms. Regions where groundwater withdrawal may have the highest influence on land subsidence, and thus permanent damage to soils, are B, C, D, I, J, and U, as well as areas in the northeastern and northcentral reaches of Mexico that share an aquifer with region D, I, or J in the United States. Therefore, impacts on groundwater resources, where steps are not taken to reduce the impacts as discussed in Chapter 3.1.3.11 of the Final EIS, may result in irreversible impacts on soils and corresponding impacts on the ability of those soils to filter nutrients, chemicals and pathogens.
- With respect to soil health and impacts related to subpart F (untreated or treated), if a farmer is permitted to use an application interval of 0 days between the application of untreated or treated manure and harvest, there would be no substantial change from the baseline condition that would result in significant impacts to soil resources.
- With respect to subpart I (grazing and wildlife intrusion taken together), in most cases, covered dual- or multi-purpose operations already have fields that are dedicated pasturelands and would not, under normal conditions, be rotated in for crop land. Any impacts to soils in these areas are most likely already occurring; therefore, no significant impacts from grazing are expected on soils under any management decision or alternative as a result of the PS PR, if finalized.

Waste Generation, Disposal and Resource Use–

- (Untreated) As discussed above, if a farmer is permitted to use an application interval of 0-days between the application of untreated manure and harvest, there would be no substantial change from the baseline condition that would result in significant impacts to waste generation, disposal, or use of the resource.
- (Treated) The proposed condition would be similar to the existing condition. No impacts would be associated with this alternative and corresponding management decisions. The use of chemical fertilizers in place of treated BSAs of animal origin as a nutrient source is unlikely to occur under this alternative because the alternative does not restrict the timing of the use of BSAs, but would impose a requirement to apply in a manner that does not contact covered produce.

Air Quality and Greenhouse Gases –

- There are minimal adverse environmental impacts (not significant) associated with air quality and GHGs are not expected to contribute to air emissions of criteria pollutants or GHG emissions that may result in considerable public health concerns at a regional or national level.

Socioeconomic and Environmental Justice –

Major cost summary

Estimates prepared by FDA in the 2014 supplemental PRIA put the total cost of implementing the provisions of the PS PR at $386.23 million nationwide for businesses with an average annual monetary value of produce sold during the previous three-year period of more than $25,000 (FDA, 2014b).

Cost and related environmental impacts

- The average projected per-farm cost of complying with the provisions of the PS PR is approximately $11,000, though this estimate is much lower (*i.e.*, approximately $4,500) for very small farms. Small and very small farms may not be able to afford the added cost burden of complying with the provisions of the PS PR. It is anticipated that these farms, if they are not able to qualify for an exemption to reduce the cost of compliance, would be the most likely to make management decisions that would result in them not being subject to the provisions of the PS PR.
- As discussed under Chapter 4.2, based on the comments FDA has received in response to the 2013 proposed rule and supplemental proposed rule, FDA does not expect farmers to decide to cease growing covered produce as a preferred management decision except in select instances which are often driven by outside pressures such as a program run by the State of California that pays farmers to keep land fallow in order to divert water to the cities. This is not a re-zoning of the land; rather, that land is essentially reserved for future alternative agricultural uses. FDA received additional comments during the comment period for the Draft EIS on the likelihood of such a management decision to occur; however, nothing in those comments changes the conclusions made in this section of the Final EIS (see Appendix E for further information).
- If non-covered produce or other agricultural crops that are not produce are grown, requirements to maintain certain water quality conditions would be dependent on any existing state regulations or industry marketing agreements. The type of crop a farmer may select to grow would also be dependent upon the region's climate, soils, water availability, and may involve a decision whether the existing farm's equipment and infrastructure would be sufficient, or would need to be updated, modified, or bought to accommodate a new type of crop.
- Under certain conditions, where very small farms are involved and costs may be a larger factor, some farms may decide to stop growing crops altogether. However, this scenario would be most likely for very small farms as well as livestock operations that grow small amounts of covered produce (although many such diversified farming-livestock operations would likely be excluded based on the new proposed monetary threshold for excluded farms applied to sales of produce only rather than sales of food). There are no data to suggest under what conditions specifically such a management decision may occur, and there are no data available to quantify or qualify any related indirect impacts.

- Also related to subpart E, there may be additional costs (and associated socioeconomic impacts) from those projected in FDA's PRIA (FDA, 2013b and 2014b) if farmers add a post-harvest mechanism (*e.g.*, FDA-approved wash or rinse) to achieve microbial die-off or removal.
- Under subpart F, since there is no substantial change from the existing conditions, we do not expect additional costs (and associated socioeconomic impacts) associated with this provision.

Environmental justice –

- **Minority groups:** The overall cost of compliance for farms could potentially result in higher produce prices for consumers, including minority consumers. However, we expect that demand for produce commodities would eventually be met by other growers in the region, growers in other regions, or international suppliers. As a result, we expect commodity prices to stabilize.

  As discussed in Chapters 1.9, 3.7, and 4.1, Environmental Justice impacts related to the PS PR are assessed for minority principal operators and minority farmworkers.

  When considering the thresholds established in Chapter 3.7 for identifying potential impacts to minority principal operators, regions that are important for identifying potential impacts to minority principal operators are regions A, B, C, D, W, and V. Of these regions, regions B and C are major produce growing regions (see Chapter 1.7). Information for minority farmworkers is provided below.

- **Principal operators:** Like all principal operators, minority principal operators would need to make management decisions regarding whether to comply with the provisions of any final rule or to cease growing covered produce. As noted above, very small farms are more likely than larger farms to decide to stop growing covered produce altogether if the farm manages livestock operations that also grow small amounts of covered produce; many such diversified farming-livestock operations would likely be excluded based on the proposed monetary threshold for excluded farms applied to sales of produce only rather than sales of food. Based upon the "meaningfully greater" threshold FDA established for minority populations of principal operators potentially affected by the rule, regions where minority principal operators manage very small farms that are more likely to make a management decision to cease growing covered produce are regions A, B, C, D, W, and V.

- **Minority farmworkers:** Based on the limited information on farmworkers reported by the DOL through surveys taken by that agency (see Chapter 3.7.3), regions where there are potential populations of minority farmworkers that may be impacted by the rule, if finalized, include regions C, D, I, and J. Costs incurred by farms of all sizes may result in the farm either increasing the costs of their produce for consumers, or may involve the farm principal operator terminating the employment of full-time, part-time, or seasonal worker(s) in order to defray their operating costs. With respect to the scope of this EIS (see Chapter 1.9), regions where such actions may adversely disproportionately affect minority farmworkers due to employment-related impacts, include regions C, D, I and J.

- **Native American operators:** Of all farms that are operated by Native American principal operators, whether located on or off reservations, 5.5 percent report growing vegetables, 2.4

percent report growing fruits and tree nuts, and 15 percent report growing combination crops. There may be farms that produce crops in multiple of these categories, and these categories include both covered and non-covered crops. Therefore, based on a very conservative estimate, no more than 22.9 percent of farms—the sum of these three categories—that are operated by Native American principal operators may be growing covered produce (USDA NASS, 2014a). Based on USDA NASS data (2014a), 78 percent of all Native American farms sell less than $10,000 in total sales, annually, meaning that, at most, 22 percent of farms with a Native American principal operator would be covered farms under the PS PR, if finalized. If we assume that these trends are consistent across all commodities, this means that, at most, 5 percent of farms with a Native American principal operator would be covered by the rule (22 percent of 22.9 percent is approximately 5 percent). Moreover, farms that sell less than $25,000 annually in produce—not $10,000—are not covered by the PS PR. An additional 14 percent of farms with a Native American principal operator sell less than $49,999, meaning there is a reasonable likelihood that additional farms with a Native American principal operator would not be covered by the PS PR, if finalized. It is not possible to estimate what percent of farms lie between $10,000 and $49,999 average annual sales. An additional 5 percent of Native American operated farms have less than $249,999 in total sales.

Despite the low number of total Native American owners/operators who may be covered by the rule, there is a potential that added operating costs associated with the rule would impact a disproportionate number of Native American farmers compared to farmers as a whole, given that the average income for a farm for which a Native American is the principal operator is 30 percent lower than a farm for which the principal operator is not a Native American (per the 2007 Agricultural census). The average reported agricultural product sales for Native American operated farms is $40,331, compared to an average of $134,807 for all farms. The average potential per farm cost of approximately $4,500 for very small farms could be disproportionally burdensome for farms with a Native American principal operator, as this cost would comprise approximately 11 percent of average annual sales, compared to 3 percent of the average annual sales of all farms.[4] However, the potential impacts for very small and small farms may be entirely mitigated to the extent these farms are eligible for a qualified exemption.

- **Low-income:** As discussed in Final EIS Chapter 3.7.3, this class includes any persons whose median household income is at or below the HHS poverty guidelines. The poverty threshold for a family of four in 2012 was set at $23,050. According to the ERS's data sheet, *Principal Farm Operator Household Finances by ERS Farm Typology,* in 2012, median farm operator household income, an average of the farm and off-farm household incomes of residence farms, intermediate farms, and commercial farms, was $68,298.[5] This exceeds both median U.S. household income and the HHS poverty thresholds for all HHS poverty guidelines. While there may be low-income principal operators that may be adversely impacted by the costs associated with the rule, we cannot identify a low-income population on a national or regional level.

- **Low-income farmworkers:** As discussed under minority farmworkers, impacts may involve the farm principal operator terminating the employment of full-time, part-time, or seasonal

[4] $4,500 divided by $40,331 equates to approximately 11 percent.
[5] There is limited data for principal farm operator income other than on a national level.

worker(s) in order to defray their operating costs. Consistent with the scope of the EIS (see Chapter 1.9), based on data provided by the DOL (information reported for California) (DOL, 2000 and 2005), region C has populations of low-income farmworkers that may be disproportionately impacted by the rule. Note that other regions may experience similar impacts, but there is not enough data available to understand which regions may specifically be impacted.

Human Health–

Foodborne illnesses prevented

- FDA estimates, in the 2014 PRIA to the PS PR, that the number of foodborne illnesses prevented when considering the rule as proposed, all provisions, is 1.57 million, annually (FDA, 2014b). This represents a significant beneficial outcome to human health because the rule as proposed is likely to minimize the risk of serious adverse health consequences or death from covered produce.

Human health impacts

- Under subpart E, EPA-registered pesticide products are evaluated to determine potential environmental effects and potential impacts to human health specific to their use. With respect to the use of chemical pesticides, FIFRA mandates that EPA regulate the use and sale of pesticides to protect human health and preserve the environment. There is the possible risk of chemical exposure to site workers that may have to handle pesticides prior to application, but these risks are minimized when using proper handling techniques including using recommended personal protective equipment in accordance with labeling requirements or product recommendations (*e.g.*, chemically resistant gloves to avoid exposures that may otherwise cause unreasonable health effects) as described by the manufacturer. We do not expect impacts to human health and safety to be significant from the use of these products.

Alternatives Analysis under subpart A

By applying the potential environmental impacts from each of the alternatives that would best fulfill FDA's statutory mission and responsibilities (see above), we may now identify the potential environmental and related socioeconomic impacts to each of our alternatives that were first identified in Section ES.3 (and Final EIS Chapter 2.1, subpart A). A comparison of potential impacts is provided below and summarized in Table ES-1.

Table ES-1. Comparison of potential impacts by alternative for subpart A

		≤ $25,000 * total produce excluded Alternative I	≤ $50,000** food excluded Alternative II	≤ $100,000** food excluded Alternative III	≤ $25,000 covered produce excluded Alternative IV
Comply with the rule	Covered Farms	35,503	28,253	20,140	Slightly fewer than Alternative I
	Excluded Farms	130,204	161,384	169,497	Slightly greater than Alternative I
	Environmental impacts (Chapters 4.1 – 4.7)	Greater than baseline	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Economic impacts (domestic costs annually)	$540.49 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Domestic benefits (health-related cost savings)	$930 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Public health benefits (foodborne illnesses prevented annually)	1.57 million	Less than Alternative I (less foodborne illnesses prevented)	Less than Alternative II (less foodborne illnesses prevented)	Slightly fewer than Alternative I (less foodborne illness prevented)
Switch to non-covered crop	Covered Farms	Less than 35,503	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Excluded Farms	Greater than 130,204	Greater than Alternative I	Greater than Alternative II	Slightly greater than Alternative I
	Environmental impacts (Chapters 4.1 – 4.7)	Less impacts compared with complying	Less impacts compared with Alternative I	Less impacts compared with Alternative II	Slightly fewer than Alternative I
	Economic impacts (domestic costs annually)	Less than $540.49 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Domestic benefits (health-related cost savings)	Less than $930 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Public health benefits (foodborne illnesses prevented annually)	Less than 1.57 million	Less than Alternative I (less foodborne illnesses prevented)	Less than Alternative II (less foodborne illnesses prevented)	Slightly fewer than Alternative I (less foodborne illness prevented)

*As updated in the 2014 supplemental PRIA (FDA, 2014b).
**The associated estimates are found within the 2013 PRIA (FDA, 2013b).

Under the Preferred Alternative (Alternative I) more farms would be covered than if the average annual monetary value threshold for exclusion of farms were higher (as in Alternatives II and III) or if the threshold was changed to include sales of covered produce only (as in Alternative IV).

For any alternative the expected environmental outcome may be as follows:

- Significant current and ongoing adverse impacts such as reduced water availability, water-table declines, soil subsidence and increased costs for finding and maintaining access to water, resulting from groundwater withdrawals are presently experienced in regions B, C, D, I, J, and U, and represent the current condition, absent of any final rule. Any action in these regions that would cause a farmer or any entity to draw from groundwater instead of surface water could

exacerbate the current environmental conditions, generally. Under such conditions, individuals on Native American reservations in regions B and C may be disproportionately adversely impacted as a result of continued groundwater drawdown. Issues relating to groundwater depletion and land subsidence could also be experienced in the northeastern and northcentral reaches of Mexico that share an aquifer with region D, I, or J in the United States. We consider impacts from actions that result in groundwater drawdown to be significant in regions where current conditions for groundwater depletion have significant environmental impact. Such impacts are best considered under the cumulative impacts section, Section ES.9 (or Chapter 5 of the Final EIS). However, such impacts are not expected to occur as a result of this rule based on the flexibility in meeting the proposed water quality standard (see the following bullets). The flexibility in meeting the proposed water quality standard is likely to limit the need to use chemical treatment of a water source with poor water quality. It is also likely that a farmer might add a post-harvest mechanism to allow for added microbial die-off or removal.

- Moreover, reactions and verbal comments from industry and trade groups that FDA has received on the supplemental proposed rule suggest that the new proposed provisions for microbial die-off and/or removal to achieve the proposed water quality standard considerably reduce the perceived need to change water source in order to comply with Alternative I under subpart E. In addition, many farmers have entered into marketing agreements that are the same as, or operate under more stringent numeric water quality standards than, those proposed in the PS PR. FDA received no conflicting comments to the same topic during the Draft EIS public comment period.
- Other environmental impacts nationwide are expected to be not significant, with the exception of human health and safety where there would be significant beneficial outcome to human health. Impacts associated with biological and ecological resources may potentially result from the use of chemical treatments (*e.g.*, the use of pesticides and herbicides); however, wildlife, vegetation, and wetlands would be resilient to these impacts. There are minimal adverse environmental impacts (not significant) associated with air quality and GHGs are not expected to contribute to air emissions of criteria pollutants or GHG emissions that may result in considerable public health concerns at a regional or national level.

Given this analysis, FDA expects the PS PR, if finalized as proposed, would have significant adverse environmental impacts on groundwater and soil resources that are reviewed within the scope of this EIS.

For any alternative where fewer farms are covered by the rule (fewer than Alternative I), the potential outcomes may be as follows:

- The expected costs of complying with the rule nationwide would decrease, but the expected per farm costs are anticipated to remain the same as Alternative I.
- The expected environmental impacts, both adverse and beneficial, would decrease nationwide, but not to the extent that would reduce any significant impacts to a less than significant level.
- The expected number of foodborne illnesses would decrease, which means fewer public health benefits would be experienced.

ES.7 Preferred Alternative

This section addresses the Agency's preferred alternative. As defined by the Council on Environmental Quality (CEQ), the "agency's preferred alternative" is "the alternative which the agency believes will best "fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors" (CEQ, 1981). The concept of the "agency's preferred alternative" is different from the "environmentally preferable alternative," although in some cases an alternative may be both. As previously discussed, given the diverse nature of agricultural practices, we analyzed the potential impacts of alternatives for each of the potentially significant provisions both individually and cumulatively. This analysis allowed for a more comprehensive understanding of the role that each of the provisions plays in terms of environmental impacts and human health benefits.

FDA used a two-step process to identify the preferred alternative for the Final EIS. In the first step, FDA established a range of reasonable alternatives for each potentially significant provision. Each alternative reflects a science-based minimum standard established for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities, to minimize the risk of serious adverse health consequences or death (see 21 U.S.C. 350 h(a)). At the second step, FDA selected the alternative for each provision for use in the aggregate analysis in Section ES.6 (or see Final EIS Chapter 4.7) that FDA believes would best "fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors" (CEQ, 1981), with the exception of untreated BSAs of animal origin. FDA has previously indicated it would defer decision on a minimum application interval for untreated BSAs of animal origin and therefore has not identified an alternative that would best meet the statutory mission and responsibilities. For the purpose of the aggregate analysis, in the absence of a decision on the alternative which would fulfill the statutory mission, the impacts associated with the 0 day application interval were included as the environmental impacts associated with this alternative. Such impacts are indicative of current practice and any minor shifts in this practice that may be anticipated.

FDA considered the management decisions that were analyzed for each potentially significant provision in Section ES.6 (Final EIS Chapter 4). Section ES.6 (or Final EIS Chapter 4.7.1) contains FDA's analysis of the most likely management decisions to occur under subpart A.[6] The rationale for these management decisions is discussed in detail for subparts E, F, I, and A in the section that follows. Management decisions were identified in consultation with USDA and after consideration of public comment on the PS PR.

[6] As discussed in Section ES.6 and in greater detail in Chapter 4.7 of the Final EIS, unlike with standards directed at specific potential routes of pathogen introduction (*e.g.*, subparts E, F, and I), proposed § 112.4 in subpart A establishes the value of produce sold above which a farm growing covered produce would be subject to the provisions of the rule (*i.e.*, covered farms). Covered farms would be required to either comply with the provisions of the rule, including through the use of the management decisions described in Final EIS Chapters 4.2 through 4.6, or switch to crops that are not covered by the proposed rule. In other words, complying with the rule would mean that a farmer would have to abide by the provisions of the rule, except where the grower would qualify for certain exclusions from coverage of the rule.

Taken together, the Agency's preferred alternative for the Final EIS can be summarized and stated as follows:

Except in cases where the grower would qualify for certain exclusions from coverage of the rule, if you are a farm or farm mixed-type facility with an average annual monetary value of produce (as defined in proposed 21 CFR 112.3(c)) sold during the previous 3-year period of more than $25,000 (on a rolling basis), you are a "covered farm" that must comply with the provisions of 21 CFR part 112 when conducting a covered activity on "covered produce" (proposed 21 CFR 112.4, as amended by the supplemental proposed rule), including:

1) When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method that includes root crops that are irrigated using low-flow methods such as drip irrigation, if you find (through testing using one of the appropriate analytical methods as described in subpart N of the proposed rule) that the estimate of the statistical threshold value (STV) of samples exceeds 410 colony forming units (CFU) of generic *E. coli* per 100 ml of water or that the geometric mean (GM) of samples exceeds 126 CFU of generic *E. coli* per 100 ml of water, you must either apply a time interval between last irrigation and harvest using a microbial die-off rate of 0.5 log per day and/or a time interval between harvest and end of storage using an appropriate microbial die-off or removal rates, including during activities such as commercial washing (or follow other options as described in § 112.44(c)) (proposed § 112.44(c), as amended by the supplemental proposed rule) (see Section ES.4 or Final EIS Chapter 2.1, subpart E, Alternative IV-a);

2) If you are using untreated BSA of animal origin it must be applied in a manner that does not contact covered produce during application and minimizes contact after application (see Section ES.4 or Final EIS Chapter 2.1, subpart F Untreated, Alternative II);

3) If you are using a treated BSA of animal origin (by a composting process in accordance with the requirements FDA proposed in § 112.54(c) to meet the microbial standard proposed in § 112.55(b)) and applying it in a manner that minimizes the potential for contact with covered produce during and after application, the minimum application interval is zero days (proposed § 112.56(a)(4)(i), as amended by the supplemental proposed rule) (see Section ES.4 or Final EIS Chapter 2.1, subpart F Treated, Alternative I);

4) At a minimum, if animals are allowed to graze or are used as working animals in fields where covered produce is grown, and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, the grower must take the following measures: (a) an adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed to ensure the safety of the harvested crop; and (b) if working animals are used in a growing area where a crop has been planted, measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce (proposed § 112.82) (see Section ES.4 or Final EIS Chapter 2.1, subpart I Domesticated Animal Grazing, Alternative I); and

5) While taking into consideration that the produce safety rule neither authorizes any violations of the Endangered Species Act (16 U.S.C. 1531–1544) nor requires covered farms to take measures to exclude animals from outdoor growing areas or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages, if under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce, you must monitor those areas that are used for a covered activity for evidence of animal intrusion:

(1) As needed during the growing season based on:
(i) The covered produce; and,
(ii) The grower's observations and experience; and,
(2) Immediately prior to harvest.

If animal intrusion, as made evident by observation of significant quantities of animals, animal excreta or crop destruction via grazing occurs, the grower must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112 (proposed § 112.83(a) and (b) and, as proposed in the supplemental proposed rule, proposed § 112.84) (see Section ES.4 or Final EIS Chapter 2.1, subpart I Wild Animal Intrusion, Alternative I).

6) Comply with minimum-science based standards directed at:[7]
(1) Personnel Qualifications and Training, including by establishing requirements for training of personnel who handle (contact) covered produce or food-contact surfaces (proposed §§ 112.21 to 112.30) to ensure that personnel who operate or work for covered businesses are appropriately trained in food safety practices;
(2) Worker Health and Hygiene (proposed §§ 112.31 to 112.33), including by establishing hygienic practices and other measures needed to prevent persons, including visitors, from contaminating produce with microorganisms of public health significance;
(3) Growing, Harvesting, Packing, and Holding Activities, including by establishing that you take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, and ensure that food-packing material that is used in covered activities is clean and adequate for its intended use (proposed §§ 112.111 to 112.116);
(4) Equipment, tools, and buildings, including equipment and tools that contact covered produce and instruments and controls (including equipment used in transport), buildings, domesticated animals in and around fully-enclosed buildings, pest control, and hand-washing and toilet facilities. The proposed standards include measures to prevent equipment, tools, and buildings, and inadequate sanitation from introducing known or reasonably foreseeable

[7] The standards identified here correspond to those proposed standards that were dismissed from detailed analysis (see Final EIS Chapter 2.2).

hazards into covered produce or food-contact surfaces (proposed §§ 112.121 to 112.140);

(5) Sprouts, including by establishing measures that must be taken related to seeds or beans for sprouting (proposed § 112.141) and the growing, harvesting, packing, and holding of sprouts (proposed § 112.142). In addition, the proposed standards require that you test the growing environment for *Listeria* spp. or *L. monocytogenes* and that you test each production batch of spent irrigation water or sprouts for *E. coli* O157:H7 and *Salmonella* species and take appropriate follow-up actions (proposed §§ 112.143, 112.144, 112.145, 112.146);

(6) Analytical methods, by establishing scientifically valid analytical methods for use to comply with relevant testing requirements (proposed §§ 112.151 and 112.152);

(7) Recordkeeping, including by establishing requirements for you to establish and keep certain records (proposed §§ 112.161 to 112.167);

(8) Variances, in which FDA proposed to set forth the procedures for requesting a variance by submitting to FDA a citizen petition using the process described in 21 CFR 10.30, specifically identifying the standard or standards from which the requesting entity is requesting a variance and identifying the specific growing conditions and science-based procedures or practices that would support a variance and FDA's review of such request (proposed §§ 112.171 to 112.182);

(9) Establishing compliance and enforcement provisions (proposed §§ 112.191 to 112.193)); and

(10) Withdrawal of Qualified Exemption, in which FDA proposed, among other provisions, procedures under which FDA may withdraw a qualified exemption applicable to a covered farm under one of two circumstances: (1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the farm that had received a qualified exemption (proposed § 112.201(a)) or (2) if FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at the farm (proposed § 112.201(b)); and procedures and circumstances under which FDA may reinstate a qualified exemption that is withdrawn (proposed § 112.213, as proposed in the supplemental proposed rule).

ES.8 Mitigations

This section identifies mitigation measures that are intended to assist farmers affected by the rule with understanding and implementing compliance requirements associated with the rule (*e.g.*, training, outreach, education).

A mitigating factor of particular importance is FDA's development of a compliance strategy that will be used for the implementation of the final rule. Education and technical assistance (including FDA-issued guidance documents) are the principal components of the compliance strategy. FDA believes that a comprehensive compliance strategy focused on education and technical assistance for farmers can help alleviate any uncertainty about requirements of any final rule, which, in turn, can help ensure that the provisions of the final rule are appropriately followed.

FDA has diligently been working toward this effort since FSMA was enacted. For example, in May 2014, FDA published the "Operational Strategy for Implementing the Food Safety Modernization Act (FSMA): Protecting Public Health by Strategic Implementation of Prevention-Oriented Food Safety Standards," which describes the guiding principles for implementing all aspects of FSMA, including produce safety standards (FDA, 2014a). In addition, FDA held a two-day public meeting entitled "FDA Food Safety Modernization Act: Focus on Implementation Strategy for Prevention-Oriented Food Safety Standards" on April 23-24, 2015, to present FDA's current implementation plans. The meeting was announced in the *Federal Register* on March 24, 2015, and included information on how to submit comments to a docket established to obtain comments on the FSMA implementation work plans (80 Fed. Reg. 15612).

With respect to education and technical assistance, FDA firmly believes that compliance cannot be effectively achieved based on FDA's efforts alone. Rather, FDA is building a network of partners that can assist with providing education and technical assistance to the farming community. This network involves collaboration with various institutions primarily via cooperative agreements, partnerships, and alliances—each of which is, in turn, described more fully below.

One of the key members of the network is the National Association of State Departments of Agriculture (NASDA), in which all 50 U.S. State Departments of Agriculture and the territories of American Samoa, Guam, Puerto Rico, and the U.S. Virgin Islands participate. In September 2014, FDA announced that a new cooperative agreement has been established between FDA and NASDA that will provide critical information on local produce growing, harvesting, packing, and holding, in an effort to assist states with aligning their requirements with the final rule (FDA, 2014c). Specifically, the cooperative agreement will "provide the funding and support necessary to determine the current foundation of state law, the resources needed by states to implement the produce safety rule, as well as develop a timeline for successful implementation once the rule is finalized" (FDA, 2014c).

While education and technical assistance would be available to everyone in the farming community who would be required to comply with any final rule, special focus has been put on growers and farmers with small operations. Accordingly, in January 2015, FDA announced that it has formed a collaborative partnership with the USDA's National Institute of Food and Agriculture (NIFA) to administer and manage the "National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program," a grant program that will provide funding so that small farm growers and owners receive adequate training, education, and technical assistance (FDA, 2015a).

The announcement also lists training grant application types that will be prioritized: "Priority will be given to those submitting grant applications to train owners and operators of small and medium-size farms; farmers just starting out in business; socially disadvantaged farmers; small food processors; small fruit and vegetable wholesalers; and farms that lack access to food safety training and other educational opportunities" (FDA, 2015a). The NIFA-FDA program will also award grants to establish one national coordination center that will coordinate the overall program and four regional centers that will reach out to the local communities. Moreover, the regional centers will coordinate with each other through the national coordination center which will further make certain that the information is provided throughout all areas of the country (FDA, 2015a). In addition to NIFA, FDA is partnering with multiple other organizations to assist with the implementation of the final rule such as land grant University Cooperative Extension Services, community based organizations, and food safety professional organizations (FDA, 2015b).

Currently, FDA is also working with the Produce Safety Alliance (PSA) and the Sprout Safety Alliance (SSA) to develop training to help the farming community understand and comply with the final rule. The PSA, a collaborative effort with Cornell University, is currently developing training materials on the rule's requirements. The SSA, centered at the Illinois Institute of Technology, is also developing training materials specifically designed to assist sprout growers (FDA, 2015b). In addition to classroom training, FDA is collaborating with NASDA to develop a voluntary on-farm assessment program. These assessments are intended to be conducted before the compliance period is in effect to assist farmers in understanding what the rule requires before the mandatory compliance date arrives (FDA, 2015c).

Along with education and technical assistance, FDA-issued guidance documents round out the principal components of the compliance strategy. Section 419(e) of the FFDCA requires FDA to issue guidance documents to assist the farming community with rule compliance. FDA anticipates that the principle guidance document for compliance with the rule will be published in 2016, with other guidance documents following as resources allow. FDA will provide opportunity for public comment on the draft guidance documents so FDA can gain input from the affected community before issuing any final guidance.

ES.9 Cumulative Impacts

Similar to the comparison of environmental impacts conducted in Section ES.6 (and corresponding to Final EIS Chapter 4.7), the cumulative impacts analysis was conducted for alternatives under subpart A because, if a farm is covered under subpart A, then the other provisions of the rule apply.

The potential environmental impacts are associated with management decisions and the alternatives which the agency believes will best "fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors" (CEQ, 1981). The summary of environmental impacts is subdivided by resource component (*e.g.*, water resources, air quality, biological and ecological resources). The cumulative impacts analysis looked at those resource components and evaluated them together with programs and actions that occur within the same relative time scope of the proposed rule (see Final EIS Chapters 5.3 and 5.4). Final EIS

Chapter 5.5 provides a full evaluation of the potential "cumulative impact" on the environment that results from the incremental impact of FDA's proposed action when added to other past, present, and reasonably foreseeable future actions that are discussed in Chapters 5.3 and 5.4. Therefore, the potential environmental impacts that are summarized below, in some cases, may be more severe than the impacts that were assessed in Chapter 4.7 and that are summarized in Section ES.6. Likewise, certain agency and/or industry actions may have beneficial effects, and thus may reduce the potential severity of a potential environmental impact.

The added cumulative effects of past, present and reasonably foreseeable actions are not anticipated to raise the significance of potential impacts on the human environment, based on the full analysis conducted in Chapter 5 of the EIS; the possible exception is related to groundwater drawdown. Therefore, Table ES-1 above is fairly representative, on a qualitative basis, of the potential cumulative impacts expected if the PS PR is implemented.

For any alternative where fewer farms would be covered by the rule (see Table ES-1, Alternatives II, III, and IV), the potential cumulative environmental, socioeconomic, and public health impacts would be less than what may occur under Alternative I.

Water Resources - Based on our qualitative analysis, we do not consider impacts to water resources to be significant because the flexibility in meeting the proposed water quality standard is likely to limit the need to use chemical treatment of a water source with poor water quality. It is also likely that a farmer might add a post-harvest mechanism to allow for added microbial die-off or removal. The potential exception is related to groundwater withdrawal, where significant adverse long-term impacts to water availability and soils (related to the irreversible impacts from land subsidence) may continue to occur in regions B, C, D, I, J, and U, as well as parts of northeastern and northcentral Mexico that share an aquifer with region D, I, or J, as a result of excessive groundwater use. These effects are the result of the current condition and projected ongoing impacts related to water use throughout the U.S., and any further contribution to these impacts would be significant. Individuals on Native American reservations in regions B and J may be disproportionately adversely impacted as a result of continued groundwater drawdown and reduced access to water on reservations.

The issue of downstream degradation of water quality by salts, agrochemicals, and toxic leachates is a serious environmental problem. Regions that grow covered produce and that are already experiencing high exceedances in state surface water quality levels based on CWA Section 303(d) requirements (33 U.S.C § 1313(d)) (refer to Final EIS and compare Figure 3.1-15 in Chapter 3.1.3.9 to Figure 1.7-4 in Chapter 1.7) and groundwater quality impairments (primarily from coliform bacteria) include regions A, B, C, L, R, T, and U (refer to Final EIS and compare Figures 3.1-16 and 3.1-17 in Chapter 3.1.3.9 to Figure 1.7-4).[8]

Biological and Ecological Resources - FDA does not anticipate significant impacts to biological and ecological resources as a result of the rule because there would be no anticipated impact to the sustainability of vegetation or wildlife at the regional or national level. Any impacts to wetlands or waters would not be significant because water quality conditions would be expected to return

[8] Regions A, B, C, L, R, T, and U represent the majority of the east and west coast states.

to ambient conditions. In addition, the prevalence, use and effectiveness of measures that promote private and public conservation may further minimize any potential cumulative environmental effects.

Soils - Relative to soil quality and subpart F, there would be no substantial change from the baseline condition that would result in significant impacts to soil resources. Potential impacts related to land subsidence are summarized under water resources, above.

Waste Generation, Disposal, and Resource Use – Waste generation, disposal and resource use would remain substantially unaffected from baseline conditions, and therefore, we do not expect additional environmental impacts.

Air Quality and Greenhouse Gases - With respect to air quality and GHGs, any contributions of air emissions of criterial pollutants or GHG emissions are not expected to result in considerable public health concerns at a regional or national level; therefore, we do not expect significant impacts.

Socioeconomics and Environmental Justice - Based on the 2013 PRIA and 2014 supplemental PRIA (FDA 2013b and 2014b, respectively), and based on our qualitative analysis, small and very small farms may be more adversely affected by such costs; however, these farms may be eligible for qualified exemptions, which would effectively mitigate costs of the rule. While small and very small farms may not be able to afford this added cost burden, farms that are not able to qualify for an exemption to reduce the cost of compliance would be the most likely to make management decisions which would either result in them not being subject to the provisions of the PS PR or that would make them exempt from the provisions. Based on the comments that FDA received on the supplemental proposed rule, FDA does not expect that individual primary farm operators would cease growing covered produce as a preferred management decision except in select instances which are often driven by outside pressures unrelated to this rule (an example cited in Final EIS Chapter 4.7 includes the state of California that pays farmers to keep land fallow in order to divert water to the cities).

If non-covered produce or other agricultural crops that are not produce are grown, requirements to maintain certain water quality conditions would be dependent on any existing state regulations or industry marketing agreements.

With respect to subpart F, since there is no substantial change from the existing conditions, then there are no additional costs associated with this provision that may result in impacts to farm employment or loss of income.

Minority primary operators

Principal operators for very small farms are generally more likely than primary operators of larger farms to make management decisions to stop growing crops altogether if the farm manages livestock operations that also grow small amounts of covered produce, although many such diversified farming-livestock operations would likely be excluded based on the monetary threshold for excluded farms applied to sales of produce only rather than sales of food. Because of the

potential exclusion based on sales or eligibility for qualified exemptions that may be available to very small and small farms, and because there are management decisions available to all covered farms that may reduce the impacts related to employment or income, we do not expect there to be disproportionate cumulative impacts to minority primary operators. Any potentially adverse impacts to minority primary operators are more likely to occur in regions A, B, C, D, W and V.

Minority farmworkers

As discussed in Chapters 3.7 and 4.7, and above, costs incurred by farms of all sizes may result in the farm either increasing the costs of their produce for consumers, or may involve the farm primary operator terminating the employment of full-time, part-time, or seasonal worker(s) in order to defray their operating costs. Regions were such actions may adversely disproportionately affect minority farm workers include regions C, D, I, and J.

Native American operators

As discussed in Chapter 4.7, based on available data, it appears that no more than, 5 percent of farms with a Native American principal operator would be covered by the rule. Despite this relatively low number of total Native American owners/operators who may be covered by the rule, there is a potential that added operating costs associated with the rule would impact a disproportionate number of Native American farmers compared to farmers as a whole, given that the average sales for a farm with a Native American principal operator is 30 percent lower than a farm with a non-Native American principal operator farm (per the 2007 Agricultural census). The average reported agricultural product sales for Native American operated farms is $40,331, compared to an average of $134,807 for all farms. The average potential per-farm cost of approximately $4,500 could be disproportionately burdensome for Native American operated farms as it would comprise approximately 11 percent of their average annual sales, compared to 3 percent of the average annual sales of all farms.[9] However, the potential impacts for very small and small farms may be entirely mitigated to the extent these farms are eligible for a qualified exemption; therefore, potential incremental cumulative impacts may also be mitigated and would not be considered significant such that Native American principal operators would not be disproportionately affected by the rule.

As discussed in Chapter 4.7 and the discussion above related to water availability, individuals on Native American reservations in regions B and J may be disproportionately adversely impacted as a result of continued groundwater drawdown. These conditions are a result of current and projected ongoing impacts related to water use throughout the U.S., and are anticipated to occur even if a final rule were not enacted.

Low-income farmworkers

Regions where such actions may adversely disproportionately affect low-income farmworkers include region C.

For any alternative where fewer farms would be covered by the rule (Alternatives II, III, and IV, see Table 5.5-1) the potential cumulative environmental, socioeconomic, and public health impacts would be less than what may occur under Alternative I.

[9] $4,500 divided by $40,331 equates to approximately 11 percent.

- The expected annual economic impacts nationwide would decrease but the expected per-farm costs are anticipated to remain the same as Alternative I.
- The expected environmental impacts, both adverse and beneficial, would decrease nationwide, but not to the extent that would reduce any already significant impacts to a less than significant level.
- The expected number of foodborne illnesses prevented would decrease, which means fewer public health benefits would be experienced.

ES.10 Decision to be Made

FDA considered public and agency comments received during the Draft EIS public comment period. The Draft EIS was followed by the Final EIS. FDA evaluated the potential alternatives and the environmental impacts of each, including the related socioeconomic and human health effects, as presented in the Final EIS. This evaluation will be reflected in a Record of Decision (ROD).

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CHAPTER 4

CHAPTER 5

1.0 Introduction, Purpose, and Need

1.1 Introduction

The United States (U.S.) Food and Drug Administration (FDA), which is an Operating Division within the U.S. Department of Health and Human Services (HHS), is responsible for protecting public health by assuring the safety and security of human and veterinary drugs, biological products, medical devices, tobacco, foods, cosmetics, and products that emit radiation (FDA, 2013a).

Globalization,[1] advancements in science and technology, and shifts in consumer expectations continually drive changes throughout human and animal food systems, which often results in unforeseen challenges to public health and consumer protection. While some of these shifts may have added benefit to consumers (*e.g.*, increased choice or selection of foods, food availability, and in some cases lower prices), FDA reports that foodborne illnesses continue to have a substantial impact on public health with an estimated 48 million illnesses occurring annually (78 Fed. Reg. 3504 at 3506, January 16, 2013).

Congress recognizes the unique challenges faced by FDA in the area of food safety in the 21st century and, in 2011, enacted the Food Safety Modernization Act (FSMA) to meet those challenges. FSMA directs FDA to build a new food safety system based on the public health principle of comprehensive prevention, an enhanced focus on risk-based resource allocation, and partnership across the public and private sectors to minimize food and feed hazards from farm to table (FDA, 2012b). As such, FSMA gives FDA the public health mandate to establish standards for the adoption of modern food safety prevention practices by those who grow, process, transport, and store food; FSMA also provides FDA the authorities and oversight tools aimed at providing solid assurances that those practices are being carried out by the food industry on a consistent, on-going basis (FDA, 2014a).

Congress specifically mandated through FSMA that " . . . the Secretary [of HHS, and by delegation, FDA], in coordination with the Secretary of Agriculture and representatives of State departments of agriculture (including with regard to the national organic program established under the Organic Foods Production Act of 1990), and in consultation with the Secretary of Homeland Security, shall publish a notice of proposed rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death" (section 419(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S. Code (U.S.C.) § 350h(a)(1)(A)). Further, FSMA mandates that " . . . the Secretary [of HHS, and by delegation, FDA] . . . adopt a final regulation to provide for minimum science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits or vegetables, that are raw agricultural commodities, based on known

[1] More than $2 trillion worth of FDA-regulated products are manufactured in more than 300,000 foreign facilities in over 150 countries. The United States imports approximately 50 percent of its fresh fruit and 20 percent of fresh vegetables (FDA, 2012a).

safety risks, which may include a history of foodborne illness outbreaks" (section 419(b)(1) of FFDCA (21 U.S.C. § 350h(b)(1))).

On January 4, 2013, FDA released for public comment a proposed rule to establish minimum science-based *Standards for Growing, Harvesting, Packing, and Holding Produce for Human Consumption*. This rule is one of seven proposed rulemakings that lays the cornerstone of the prevention-based, modern food safety system that is needed to help protect human health from foodborne illness associated with the consumption of contaminated produce. FDA published this proposed rule in the *Federal Register* on January 16, 2013 ("the 2013 proposed rule"), for codification in the Code of Federal Regulations (CFR) at 21 CFR Part 112 (78 Fed. Reg. 3504). On March 20, 2013, FDA issued a notice to correct technical errors and errors in reference numbers cited in the 2013 proposed rule (78 Fed. Reg. 17155). Subsequent to the publication of the 2013 proposed rule, extensive information received in public comments led to significant changes in FDA's thinking. As a result, on September 29, 2014, FDA issued a supplemental notice of proposed rulemaking ("the supplemental proposed rule"), amending certain specific provisions of the 2013 proposed rule (79 Fed. Reg. 58434). Taken together, these publications constitute FDA's proposed standards for the growing, harvesting, packing, and holding of produce for human consumption ("the Produce Safety Proposed Rule" (PS PR)). FDA has reviewed public comments to the supplemental proposed rule as well as comments submitted in response to the Draft EIS, and is considering this information to develop a Produce Safety Final Rule.

1.2 National Environmental Policy Act

The National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. § 4321 et seq.), directs that all agencies of the Federal Government include a detailed statement on the environmental impact of a major Federal action significantly affecting the quality of the human environment. The President's Council on Environmental Quality (CEQ) published regulations implementing the procedural provisions of NEPA in 40 CFR Parts 1500-1508. An "Environmental Impact Statement" (EIS) is the detailed written statement required by section 102(2)(C) of NEPA (40 CFR 1508.11). Subsequent to the publication of the CEQ regulations, FDA published regulations in 21 CFR Part 25 governing compliance with NEPA, to supplement the procedural provisions established by CEQ. Under 21 CFR 25.22, FDA determined that there are no categories of FDA actions that routinely significantly affect the quality of the human environment that would ordinarily require the preparation of an EIS. FDA further defined, in 21 CFR Part 25, subpart C, specific classes of actions that are ordinarily categorically excluded from the need to prepare an Environmental Assessment or an EIS.

The 2013 proposed rule was accompanied by a categorical exclusion under 21 CFR 25.30(j). Subsequent to the publication of the 2013 proposed rule, however, FDA reconsidered the application of the categorical exclusion after reviewing public comments to the proposed rule and determined that the preparation of an EIS was necessary. FDA published a notice of its intent to prepare an EIS, and notice of the EIS scoping period, in the *Federal Register* on August 19, 2013 (78 Fed. Reg. 50358). On April 4, 2014, FDA held a public scoping meeting to provide public attendees and interested parties with background on the 2013 proposed rule, to identify those provisions that may significantly affect the quality of the human environment, to identify

alternatives FDA was considering, and to further request public comment. Chapter 1.8 provides more detail on the public meeting as well as other public outreach activities FDA has undertaken with regard to FSMA.

FDA prepared this EIS in accordance with CEQ regulations, 40 CFR Parts 1500-1508, and FDA regulations, 21 CFR Part 25. The scope of the PS PR is broad;[2] therefore, this EIS examines potential *broad* direct, indirect, and cumulative impacts to the human environment, and includes the conterminous (enclosed within one common boundary) U.S., Alaska and Hawaii. In addition, areas outside these states examined in this EIS include Puerto Rico, U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands) (hereinafter "EIS geographical areas") (see Chapter 1.9 for full the scope of the EIS). This EIS also examines areas where potentially significant transboundary impacts could arise: namely, Mexico and Canada.

FDA assesses in this EIS the environmental (including human) and related socioeconomic impacts for those provisions that FDA has determined may significantly affect the quality of the human environment (hereinafter referred to as "potentially significant provisions"), and alternatives to those provisions. After publication of the Draft EIS, some commenters submitted additional alternatives for FDA to consider beyond those addressed in the Draft EIS. Based on its consideration of public comments, FDA did not add any new alternatives or potentially significant provisions for detailed analysis; however, Chapter 2.2 has been edited to address these suggested alternatives from commenters. FDA's responses to these comments on suggested alternatives can be seen in more detail in Appendix E.

The EIS also assesses the No Action Alternative, which is made up of baseline agricultural practices, regulations, and industry programs, as well as background environmental conditions discussed in Chapter 3. By doing so, FDA assesses the current, ongoing environmental impacts related to the growing, harvesting, packing, and holding of what would otherwise be "covered produce" in the PS PR, if FDA were not to finalize the PS PR.

1.3 Organization of the EIS

This EIS is organized by chapters. The major issues and topics of each chapter are summarized below:

Chapter 1, Purpose, Need, and Scope. This chapter identifies FDA's purpose for the PS PR and outlines the public health need for this proposed action, including the goals and objectives for meeting the stated need. This chapter also summarizes scoping activities FDA conducted prior to, and since, publishing the 2013 proposed rule, in addition to comments received during the 2013 proposed rule comment period, the official public scoping period of the EIS, and the Draft EIS comment period. This chapter further identifies the scope of the EIS and discusses those issues that FDA has eliminated from detailed study in accordance with 40 CFR 1501.7.

Chapter 2, Description of the Proposed Action and Alternatives. This chapter presents a discussion of FDA's proposed requirements, focusing on the provisions that FDA identified during

[2] The PS PR applies to covered produce that is introduced or delivered for introduction into interstate commerce.

scoping that may significantly impact the quality of the human environment. This chapter also presents alternatives to implementing each such provision, as proposed.

Chapter 3, Affected Environment. This chapter describes the background environmental conditions with respect to environmental resource components assessed in this EIS. Resource components to be addressed include 1) water resources, 2) biological and ecological resources, 3) soils, 4) waste generation, disposal, and resource use, 5) air quality and greenhouse gases, 6) cultural resources, 7) socioeconomics and environmental justice, and 8) human health and safety.

Chapter 4, Environmental Consequences. This chapter provides the methodologies and criteria by which potential environmental impacts are assessed. It also includes an assessment of the potential environmental impacts that may result from the PS PR, if finalized, as well as alternatives considered for potentially significant provisions. This chapter further identifies FDA's preferred alternative, as well as mitigation measures that are intended to assist farmers affected by the rule, if finalized as proposed, with understanding and implementing compliance requirements associated with the rule (*e.g.*, training, outreach, education).

Chapter 5, Cumulative Impacts. This chapter provides an assessment of potential environmental impacts that may result from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (federal or non-federal) or person undertakes such other actions.

Chapter 6, Potential Irreversible and Irretrievable Commitment of Resources. This chapter is related to the use of non-renewable resources and the potential impact that the use (or depletion) of these resources would have on future generations. Irreversible effects primarily result from the use or destruction of a specific resource that cannot be replaced within a reasonable time frame, such as fossil fuels.

Chapter 7, Potential Unavoidable Adverse Impacts. This chapter relates to the review of any significant unavoidable impacts for which either no mitigation or only partial mitigation is feasible.

Chapter 8, References. This chapter includes the studies, data, policies, and resources used to prepare the EIS.

Chapter 9, Acronyms and Abbreviations. This chapter defines the acronyms used throughout this document.

Chapter 10, Glossary. This chapter defines the terms used in the document.

Chapter 11, Preparers and Reviewers. This chapter includes a list of contributors, and in accordance with 40 CFR § 1502.17 includes a description of qualifications that include position/title, education, experience, and expertise.

1.4 Purpose and Need of the Proposed Action

Purpose

The purpose of establishing requirements for the growing, harvesting, packing, and holding of produce for human consumption is to minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards.

Need

Each year foodborne diseases result in an estimated 48 million people (one in six Americans) within the U.S. becoming ill, 128,000 hospitalizations, and 3,000 deaths, according to recent data from the Centers for Disease Control and Prevention (CDC) (CDC, 2014a). This is a significant burden to public health that is largely preventable. The estimated annual cost of foodborne illnesses attributable to produce is $1.865 billion (FDA, 2014b).

Pathogens (harmful disease-causing microbes) that cause many foodborne illnesses are tracked through food safety surveillance systems such as the Foodborne Diseases Active Surveillance Network (FoodNet), which is managed by the CDC (CDC, 2014b).[3] At present, public health surveillance systems and investigation networks are frequently unable to identify specific farms that may be associated with outbreaks linked to produce. The estimated number of annual foodborne illnesses attributable to produce that would be covered by the rule (Chapter 1.5), based on FDA 2013 estimates, is 2,703,144 cases (FDA, 2013b).

While it is true that most foodborne illnesses originate from raw foods of animal origin (*i.e.*, raw meat and poultry, raw eggs, unpasteurized milk, and raw shellfish), fruits and vegetables consumed raw are also of particular concern. Washing raw produce may minimize or decrease pathogen contamination, but it may not completely eliminate pathogenic contamination.[4] Based on CDC's foodborne illness investigations, and in data the agency has compiled in FoodNet, CDC published on its Food Safety Web site that food contaminated with pathogens that cause human illness can be traced to several factors, which include, but are not limited to, the following (CDC, 2014c):[5]

- Food processing under unsanitary conditions, including contaminated food or equipment touching food contact surfaces where clean food is prepared, processed, or packaged;
- Food that is washed or irrigated with water that is contaminated with animal manure or human sewage, or that comes into contact with contaminated animal manure or human sewage; and,

[3] FoodNet reports released annually document the changes in the number of people sickened in the U.S. from foodborne infections, as confirmed through laboratory tests. More information may be found at http://www.cdc.gov/foodnet/.

[4] CDC food safety statistics and information may be found at http://www.cdc.gov/foodsafety/facts.html.

[5] Other factors that are not listed here are related more specifically to foodborne illness linked to contaminated meat products (e.g., beef, poultry, and fish).

- Food that is in contact with infected humans who handle food (humans that are ill or who have unwashed hands).

Measures that can be taken to reduce the spread of harmful pathogens include the use of clean water to irrigate, process, and package food; the treatment of raw manure (biological soil amendments) through a process that is scientifically proven to decrease or eliminate pathogens, or through the application of untreated biological soil amendments in a way that minimizes pathogen transport; the promotion of proper hygienic worker training; the use of clean equipment, tools, or surfaces that may contact produce or food contact surfaces; and the promotion of proper hand-washing and hygienic decisions. Through training, reporting, and the use of best management practices, many hazards associated with microorganisms of public health concern can be controlled to reduce illnesses.

Rulemaking considerations that support the purpose and need for the proposed action

FDA considered the following factors that are relevant to the provisions that are addressed in this EIS (see below where FDA describes the provisions of the PS PR addressed in this EIS):

- Develop science-based minimum standards to minimize the risk of serious adverse health consequences or death (section 419(a)(1)(A) of the FFDCA (21 U.S.C. § 350h(a)(1)(A));
- Provide sufficient flexibility for different sizes of operations (section 419(a)(3)(A) of the FFDCA (21 U.S.C. § 350h(a)(3)(A));
- Consider existing conservation and environmental practice standards and policies established by federal natural resource conservation, wildlife conservation, and environmental agencies (section 419(a)(3)(D) of the FFDCA (21 U.S.C. § 350h(a)(3)(D)); and,
- Avoid conflicts and duplication with the requirements set by the National Organic Program (NOP) (section 419(a)(3)(E) of the FFDCA (21 U.S.C. § 350h(a)(3)(E)).

Develop science-based minimum standards to minimize serious adverse health consequences or death

FDA has determined it must establish science-based minimum standards to ensure the safe growing, harvesting, packing, and holding of fruits, vegetables, and mixes/categories of fruits and vegetables that are raw agricultural commodities, to minimize the risk of serious adverse health consequences or death (section 419(a)(1)(A) of the FFDCA).

FDA has identified the following science-based minimum standards and provisions with respect to growing, harvesting, packing, and holding of produce for human consumption, as discussed in greater detail in the 2013 proposed rule and the supplemental proposed rule:

1) (Subpart C) Standards directed to personnel qualifications and training (proposed §§ 112.21 to 112.30). Proposed subpart C would establish requirements for the qualifications

and training for personnel who handle (contact) covered produce[6] or food contact surfaces,[7] or who are engaged in the supervision thereof. Having personnel follow proper food hygiene practices, including personal health and hygiene, can reduce the potential for on-farm contamination of covered produce. Educating personnel who conduct covered activities in which they contact covered produce and supervisors about food hygiene, food safety, and the risks to produce safety associated with foodborne illnesses and inadequate personal hygiene is a simple step that can be taken to reduce the likelihood of pathogens being spread from or by personnel to covered produce.

2) (Subpart D) Standards directed to health and hygiene (proposed §§ 112.31 to 112.33). Proposed subpart D would establish hygienic practices and other measures needed to prevent persons, including visitors, from contaminating produce with microorganisms of public health significance.

3) (Subpart E) Standards directed to agricultural water (proposed §§ 112.41 to 112.50, as amended in the supplemental proposed rule §§ 112.44(c), 112.44(d), and 112.50(b)). Proposed subpart E would establish requirements applicable to agricultural water, including measures to be taken with respect to agricultural water sources, water distribution system, and pooling of water; requirements related to the treatment of agricultural water, when appropriate; requirements for testing of agricultural water, frequency of testing, and actions that can be taken based on test results; and measures to be taken for water used during harvest, packing, and holding activities.

4) (Subpart F) Standards directed to biological soil amendments (BSAs) of animal origin and human waste (proposed §§ 112.51 to 112.60, as amended in the supplemental proposed rule (79 Fed. Reg. 58434)). Proposed subpart F would establish standards directed to treated and untreated BSAs of animal origin and human waste. These standards include requirements applicable for determining the status of a BSA of animal origin; procedures for handling, conveying, and storing BSAs of animal origin; provisions regarding the use of human waste in growing covered produce; acceptable treatment processes for BSAs of animal origin applied in the growing of covered produce; microbial standards applicable to treatment processes; application requirements and minimum application intervals; and requirements specific to agricultural teas.

5) (Subpart I) Standards directed to domesticated and wild animals (proposed §§ 112.81 to 112.84, as amended in the supplemental proposed rule (79 Fed. Reg. 58434)). PS PR subpart I includes standards that would be directed to the potential for biological hazards from animal excreta to be deposited by a covered farm's own domesticated animals (such as livestock, working animals, and pets), by domesticated animals from a nearby area (such as livestock from a nearby farm), or by wild animals (such as deer and wild swine) on covered produce or in an area where the regulated entity conducts a covered activity on

[6] Covered produce is produce that would be subject to the requirements of the proposed §§ 112.1 and 112.2 and refers to the harvestable or harvested part of the crop.

[7] Food contact surfaces are surfaces that contact human food, including equipment and tools used during harvesting, packing, and holding. See Chapter 10 for a full definition of the term.

covered produce. Proposed subpart I would not be directed to the potential for biological hazards from manure that may be used as a soil amendment.

6) (Subpart K) Standards directed to growing, harvesting, packing, and holding activities (proposed §§ 112.111 to 112.116). Proposed subpart K would establish measures to take if a covered farm grows, harvests, packs, or holds both covered produce and excluded produce; measures to take during harvest activities; how to handle harvested produce during covered activities; requirements applying to dropped "covered" produce; packing covered produce; and associated food packing materials.

7) (Subpart L) Standards directed to equipment, tools, buildings, and sanitation (proposed §§ 112.121 to 112.140). Proposed subpart L would establish standards related to equipment, tools, and buildings that are used in relation to covered produce, covered activities, and transportation of covered produce; instruments and controls use to measure, regulate, or record covered produce or covered activities; construction requirements for buildings, including separating domesticated animals from buildings or areas where covered produce is grown, handled, packed, or stored; pest control; toilet facilities; hand-washing; sewage and plumbing; trash and litter; the control of animal excreta; and recordkeeping.

8) (Subpart M) Standards directed to sprouts (proposed §§ 112.141 to 112.150). Proposed subpart M would establish requirements, including those applicable to seeds or beans used to grow sprouts; measures to be taken for growing, harvesting, packing, and holding sprouts; testing requirements for the environment for Listeria species or *L. monocytogenes* and follow-up actions for positive findings; and collection and testing of samples of spent sprout irrigation water and sprouts.

9) (Subpart N) Analytical methods (proposed §§ 112.151 to 112.152). Proposed subpart N would specify methods of analysis for testing the quality of water and the growing environment for sprouts, as would be required under proposed subparts E and M if these provisions were finalized as proposed.

10) (Subpart O) Requirements applying to records that must be established and kept (proposed §§ 112.161 to 112.167). Proposed subpart O would establish the general requirements applicable to documentation and records that would need to be established and maintained under proposed Part 112, if finalized as proposed.

11) (Subpart P) Variances (proposed §§ 112.171 to 112.182). Proposed subpart P would establish the process by which variances from one or more requirements of proposed Part 112 may be requested by a State or foreign government. This subpart details the information that would need to accompany such requests, and lists the procedures and circumstances under which FDA may grant or deny such requests and modify or revoke such variances. As proposed, variances approved by FDA would be limited to the requirements of proposed Part 112 specified by FDA and would have no effect on the application of other provisions of the FFDCA.

12) (Subpart Q) Compliance and enforcement (proposed §§ 112.191 to 112.193). Proposed subpart Q would establish the overarching provisions related to compliance and enforcement activities.

13) (Subpart R) Withdrawal of qualified exemption (proposed §§ 112.201 to 112.213, as amended in the supplemental proposed rule, and including new provisions §§ 112.201(b)(1), 112.201(b)(2), and 112.201(b)(3)). Proposed subpart R establishes the procedures that would govern the circumstances and process whereby FDA may issue an order withdrawing a qualified exemption applicable to a farm in accordance with the requirements of § 112.5 and circumstances under which FDA would reinstate a qualified exemption that is withdrawn.[8]

Provide sufficient flexibility for different sizes of operations

As proposed, the PS PR would reduce the burden on small farms as compared to larger farms, in part through the use of exemptions and modified requirements. Certain small farms would be eligible for a qualified exemption based on average monetary value of produce sold and direct sales to qualified end users (proposed § 112.5). Such farms would, instead, be subject to certain modified requirements. The PS PR additionally would provide all farms flexibility to use alternative practices, processes, and procedures for certain specified requirements, provided the farm has adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement.

Consider existing conservation and environmental practice standards and policies established by federal agencies

FDA has determined that the PS PR, if finalized as proposed, would not conflict with policies monitored by other federal agencies: for example, the Endangered Species Act (ESA) of 1973, under the management and scientific authority of the U.S. Fish and Wildlife Service (USFWS); or the Clean Water Act (CWA) of 1977, under the administration of the U.S. Environmental Protection Agency (EPA). The PS PR, if finalized as proposed, would be used together with existing practices and regulations that promote environmental conservation, and FDA has invited USDA, EPA, and USFWS to provide technical assistance to FDA during the rulemaking and NEPA process (discussed in greater detail in Chapter 1.7, Scoping – Agency Involvement, Consultation, and Cooperation). In addition, this EIS assesses the potential environmental impacts associated with potentially significant provisions based on existing regulations, agency guidance, and industry practices.

Avoid conflicts and duplication with the requirements set by the National Organic Program

The NOP comes under the direction of the USDA's Agricultural Marketing Service (AMS). The final rule establishing the program and the corresponding USDA organic regulations are codified in 7 CFR Part 205. According to 7 CFR § 205.600, the program is responsible for developing national standards for organically produced agricultural products, including the National List of Allowed and Prohibited Substances (hereinafter, "National List"), which identifies substances that may or may not be used in organic production and handling operations. The program's other roles include accrediting certifying agents to certify organic producers/handlers as well as investigating

[8] Additional information on qualified exemptions is found within this EIS at Chapter 2.1, subpart A.

and/or taking action on regulatory violation complaints. The Organic Food Production Act of 1990 authorizes the establishment of the National Organic Standards Board (NOSB), a federal advisory committee, to assist in the development of standards for substances to be used in organic production and advise the Secretary of Agriculture on any other aspects of the program (7 U.S.C. 6518(a)). Generally speaking, most farms that wish to claim its products are "organic" are required by law to be certified in accordance with the organic regulations.

USDA organic regulations that apply to agricultural water and BSAs of animal origin

Agricultural Water

Water Quality: USDA organic regulations do not contain specific requirements for water that is used in organic agricultural production. However, certifying agents (who inspect and assess farming operations for compliance with USDA organic regulations) are authorized to collect and test water samples to verify that prohibited substances are not being applied through this means (7 CFR § 205.403(c)(3)). Most organic farmers default to reliance on state or local water quality standards, World Health Organization (WHO) guidelines, or Good Agricultural Practice (GAP) manuals.[9]

Water Treatment: It is important to refer back to FDA's definition of agricultural water stated above and to note that FDA has not proposed to require any specific mechanism to bring water into compliance with the proposed water quality criteria. With respect to contaminated agricultural water (except irrigation water), EPA has registered various chemical treatment options that are currently available for farmers to treat agricultural water for harvesting, holding, and packing activities; albeit fewer options are available for organic farmers who are restricted by the National List (*See* USDA organic regulations' Allowed Substances, at 7 CFR § 205.601). In order for organic farmers to remain in the NOP, any EPA-registered pesticide that could be used to treat contaminated agricultural water would need to be an allowed substance on the National List, which adheres to strict environmental criteria. The addition of synthetic substances to the National List of Allowed and Prohibited Substances must be initiated by recommendation of the NOSB. The Secretary of Agriculture cannot expand the List of synthetic substances without a proposal from the NOSB. As the NOP already allows for the use of specific chemical treatments and has the ability to expand the list of Allowed Substances at its discretion, no direct conflicts with FDA's PS PR, if finalized, are expected.

[9] GAP manuals are often prepared through partnerships between farm stewardship groups and cooperative extension offices/facilities to help small, diversified farms manage potential food safety risks while meeting the standards set in USDA's GAP/GHP certification program.

Manure

With respect to BSAs, a summary of USDA organic regulations is provided below.

Untreated: USDA organic regulations require a 120 day or 90 day application interval for untreated manure depending on whether the edible portion of a product does or does not have direct contact with the soil in which the manure is used (7 CFR § 205.203).

It should be noted that the preamble to the final rule establishing USDA organic regulations (65 Fed. Reg. 80548, 80567, December 21, 2000), when discussing the use of raw manure as a potential food safety concern, states that the standard in its rule is "not a public health standard" and that a comprehensive risk assessment of the safety of applying raw manure to human food crops was not undertaken when developing the standard. Rather, the standard was intended to be consistent with the organic industry practices at that time, and based on NOSB recommendations for organic food crop production. The preamble further states that, "Should additional research or Federal regulation regarding food safety requirements for applying raw manure emerge, AMS will ensure that organic production practice standards are revised to reflect the most up-to-date food safety standard" (65 Fed. Reg. 80548, 80567).

Treated: USDA organic regulations do not require any application interval for composted manure. They do specify criteria for composting plant and animal materials, including time, temperature, and carbon-to-nitrogen ratio (C:N) (7 CFR § 205.203(c)(2), see also National Organic Program Guidance 5021 – Compost and Vermicompost in Organic Crop Production).

1.5 Potential hazards considered

In determining the scope of the PS PR, FDA found that although there is the potential for chemical, physical, or radiological contamination of produce, rarely do the chemical and physical hazards associated with produce suggest a risk of serious adverse health consequences or death for individuals that would consume the product; FDA also found that the presence of radiological hazards in foods is a rare event and that consumer exposure to harmful levels of radionuclide hazards, outside of catastrophic events, is very low (Beru, 2012; FDA, 2011a; UNSCEAR, 2008). Therefore, the agency did not propose specific standards for these hazards in the PS PR (see 78 Fed. Reg. 3504 at 3524). Conversely, FDA's analysis of available foodborne illness outbreak data estimates 2,703,144 annual foodborne illnesses attributable to produce that would be covered by the proposed rule (FDA, 2013b). Therefore, the PS PR focuses on setting enforceable standards that are reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards and providing reasonable assurances that produce is not adulterated on account of these hazards.

1.6 Produce covered by the proposed rule

The CDC, in partnership with state and local health agencies, has had foodborne illness surveillance systems in place for decades. Surveillance methods, programs, and partnerships are

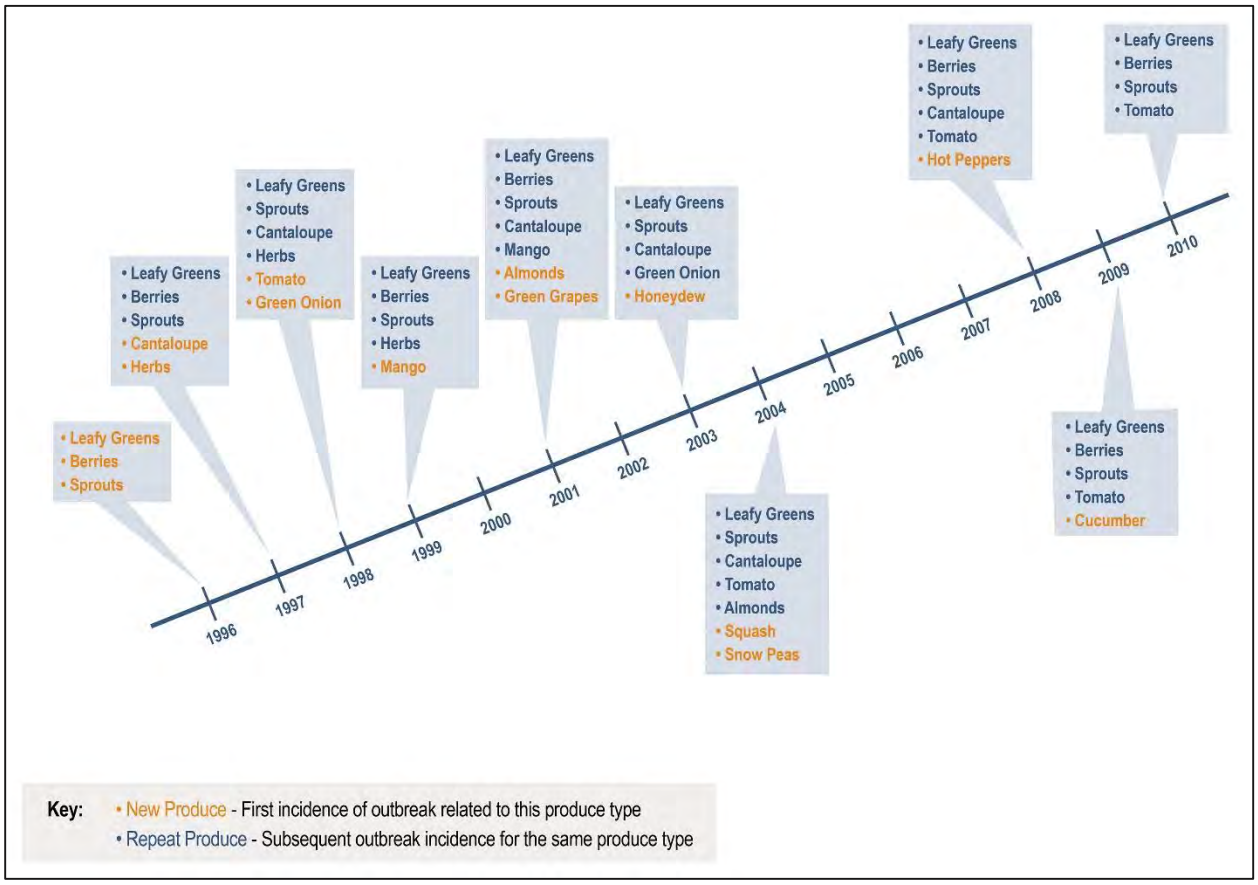
discussed extensively on CDC's Foodborne Illness Surveillance, Response, and Data Systems Web page.[10] Food commodities associated with pathogens that cause foodborne illnesses change frequently, and while pathogens are not specific to particular foods, trends presented in publicly available data from CDC show that certain raw agricultural commodities, which are not commercially processed prior to human consumption, present the greatest potential risk to spreading certain pathogens.

Food is a vehicle by which pathogens may be transported to humans. The ultimate source of harmful pathogens, however, is typically from the production environment, and more specifically enteric (from the gut or intestines) pathogens from the feces of wild animals; domesticated animals; or humans (Food and Agriculture Organization of the United Nations (FAO)/WHO, 2008). Pathogens from the animal and human gut may contaminate water, soils, equipment, food-contact surfaces, packing materials, and the food itself. A 2008 FAO and WHO study further indicated that contamination may occur from animals entering the fields where food is grown (animal intrusion), from livestock production (including manure production), as well as from water, aerosols, and dust contaminated with fecal material containing pathogens. Climate, topography, hydrology, and weather all may contribute to the extent that food commodities become contaminated. Flooding of fields may also introduce hazards to produce, as does poor hygienic practices or conditions.

It has been sufficiently demonstrated by CDC, state and local departments of agriculture, and WHO that the practices associated with growing, harvesting, handling, packing, and holding food commodities that are normally eaten raw (*i.e.*, not cooked or commercially processed prior to human consumption) are of primary concern, and these practices may be mitigated in ways to reduce the risk of pathogen contamination. Figure 1.6-1 provides a snapshot in time beginning in 1996 (CDC surveillance of outbreaks began much earlier), which shows certain produce commodities associated with pathogen outbreaks and how many distinct commodities are linked to outbreaks.

[10] CDC Foodborne Illness Surveillance, Response, and Data Systems Web page: http://www.cdc.gov/foodborneburden/surveillance-systems.html.

Figure 1.6-1. Timeline showing produce commodities associated with past outbreaks



As discussed in the 2013 proposed rule, FDA has tentatively concluded to use a regulatory framework based on practices, procedures, and processes associated with growing, harvesting, packing, and holding of all covered produce. FDA considered and rejected the option to develop a framework that (based solely on a history of outbreaks or illnesses associated with the commodity) would be applicable to individual commodities or classes of commodities. FDA explained that because foodborne illness outbreaks have regularly been associated with commodities that have previously not been linked to outbreaks, this approach carries the risk of failing to prevent future outbreaks. In addition, because only a small percentage of outbreaks are both reported and assigned to a food vehicle, outbreak data may not provide a complete picture of the commodities upon which FDA needs to focus to minimize current and future risk of illness. FDA further noted that relevant references on the subject of produce safety, as well as FDA's qualitative assessment of risk, identify common on-farm routes of contamination, such as personnel training, health, and hygiene; domestic and wild animals; BSAs of animal origin; agricultural water; and equipment and buildings. Procedures, processes and practices in each of these on-farm routes of contamination have the potential to introduce biological hazards into or onto any covered produce. Therefore, FDA proposed an integrated approach to prescribe standards for each of these on-farm routes of contamination (see 78 Fed. Reg. 3504 at 3524-3529).

Produce, meaning any fruit or vegetable (including specific mixes or categories of fruits and vegetables) grown for human consumption, and including mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and herbs, would be covered under the PS PR, if finalized as proposed. Under proposed § 112.1, FDA provided a list of commodities intended simply to provide examples of produce commonly consumed in the U.S. that would be included within the scope of the regulation. In its proposal, FDA identified three types of produce that would not be covered by the rule (see proposed § 112.2(a)). First, proposed § 112.2(a)(1) would provide an exclusion for produce that is rarely consumed raw. FDA proposed to establish an exhaustive list of specific fruits and vegetables that would be exempt from the rule (see Table 1.6-1). FDA explained that because these listed fruits and vegetables are almost always consumed only after being cooked, which is a kill-step that adequately reduces the presence of microorganisms of public health significance, these listed produce would be excluded from the requirements of the rule. Second, FDA proposed to exempt produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same ownership (proposed § 112.2(a)(2)). Third, FDA proposed to exclude produce that is not a raw agricultural commodity from this proposed rule. For example, this would exclude "fresh-cut" produce (proposed § 112.2(a)(3)).

Table 1.6-1. List of specific fruits and vegetables that would be exempt from the PS PR

List of specific fruits and vegetables that would be exempt from the rule			
- Arrowhead	- Collard greens	- Lima beans	- Rutabaga
- Arrowroot	- Crabapples	- Okra	- Sugarbeet
- Artichokes	- Cranberries	- Parsnips	- Sweet corn
- Asparagus	- Eggplant	- Peanuts	- Sweet potatoes
- Beets	- Figs	- Pinto beans	- Taro
- Black-eyed peas	- Ginger root	- Plantains	- Turnips
- Bok choy	- Kale	- Potatoes	- Water chestnuts
- Brussels sprouts	- Kidney beans	- Pumpkin	- Winter squash (acorn and butternut squash)
- Chick peas	- Lentils	- Rhubarb	- Yams

In addition to these three exemptions, FDA proposed to allow covered produce, which receives commercial processing that adequately reduces the presence of microorganisms of public health significance, to be eligible for an exemption from the requirements of the rule (proposed § 112.2(b)). FDA tentatively concluded that such commercial processing significantly minimizes the risk of serious adverse health consequences or death associated with biological hazards for such produce such that the produce can be considered to be low risk and the imposition of the requirements of the PS PR is not warranted (see 78 Fed. Reg. 3504 at 3535-3539).

Table 1.6-2 provides examples of raw agricultural commodities that are not rarely consumed raw, and due to their growing, harvesting, packing, and holding conditions, may present a high risk of pathogen contamination to humans.

Table 1.6-2. Examples of produce* covered by the Produce Safety Proposed Rule

List of produce that would be covered by the PS PR (proposed 21 CFR 112.1)				
- Almonds - Apples - Apricots - Aprium - Asian Pear - Avocados - Babaco - Bamboo Shoots - Bananas - Belgian Endive - Blackberries - Blueberries - Broccoli - Cabbage - Cantaloupe - Carambola	- Carrots - Cauliflower - Celery - Cherries - Citrus (such as clementine, grapefruit, lemons, limes, mandarin oranges, tangerines, tangors, and uniq fruit) - Cucumbers - Curley Endive - Garlic - Grapes	- Green Beans - Guava - Herbs (such as basil, chives, cilantro, mint, and parsley) - Honeydew - Kiwi Fruit - Lettuce - Mangos - Other Melons (such as canary, Crenshaw, and Persian) - Mushrooms	- Nectarine - Onions - Papaya - Passion Fruit - Peaches - Pears - Peas - Peppers (such as bell and hot) - Pineapple - Plums - Plumcot - Radish - Raspberries - Red Currant - Scallions - Snow Peas	- Spinach - Sprouts (such as alfalfa and mung bean) - Strawberries - Summer Squash (such as patty pan, yellow, and zucchini) - Tomatoes - Walnuts - Watercress - Watermelon

* Including mixes of intact fruits and vegetables

Related considerations

FDA received several comments to the 2013 proposed rule regarding produce that we proposed not to cover under the rule. Some of these comments included questions and recommendations on, among other topics, the proposed list of rarely consumed raw produce and produce that receives commercial processing. FDA is presently considering these and other comments, which may result in amendments in the relevant provisions of any final rule that may result. Any amendments would be reflected in the final rule (if a decision is made to finalize the rule). At this time, FDA does not anticipate any potential amendments to result in additional significant environmental impacts on a regional or national scale beyond what is assessed in this Final EIS. If amendments are made, FDA will explain its rationale behind those amendments in the Final Rule. Any cost-related impacts would be described in detail in an accompanying Final Regulatory Impact Analysis (FRIA), and any related environmental impacts would be summarized in the ROD.

1.7 Exposure to pathogens

Pathogens Responsible for Foodborne Illness Related to Covered Produce

Bacteria play an important role in maintaining life by decomposing organic matter, contributing to the carbon and nitrogen cycles, providing protection from diseases, and digesting food. Many bacteria are present as part of the natural human body flora and are mostly benign (not harmful), usually acting to competitively inhibit colonization by harmful microbes. Bacteria not naturally

present in the body can be transported by a variety of mechanisms through direct or indirect contact with primary and secondary sources.

Harmful, disease-causing microbes are called "pathogens." Four major microbial pathogens (shiga toxin-producing *E. coli* (STEC) O157, *Listeria monocytogenes*, Norovirus, and *Salmonella*) account for the majority of the foodborne illnesses for which a precise cause is often not determined (Newell et al., 2010). While all of the pathogens have been associated with contaminated food, ingestion of contaminated water, contact with infected animals, and unsanitary surfaces also serve as exposure pathways. Within the agricultural industry, these sources and modes of transport may include irrigation water, manure, soils, humans, and pests.

If able to bypass the defense mechanisms of a host (*e.g.*, skin, immune system), bacteria may be able to establish a parasitic relationship. Some bacteria are capable of this under the right conditions but are otherwise harmless (*i.e.*, opportunistic pathogens). Other bacteria have evolved to specifically overcome host defense mechanisms in order to establish a parasitic relationship; these are collectively referred to as bacterial pathogens. *Escherichia coli*, *Listeria monocytogenes, Salmonella,* and Norovirus outbreaks linked to produce have led to numerous deaths in the U.S. in the last several years, and all pathogens listed in Table 1.7-1 have been responsible for foodborne illnesses and hospitalizations (Scallan et al., 2011). Table 1.7-1 lists the major pathogens responsible for foodborne illness in the U.S. and includes the mode of pathogen transmission.

Table 1.7-1. Major pathogens (on produce) responsible for foodborne illness

Microorganism Name	Type	Transmission
E. coli	Bacteria	Contaminated food Consumption of unpasteurized (raw) milk Consumption of water that has not been disinfected Contact with cattle, or contact with the feces of infected people
Listeria monocytogenes	Bacteria	Contaminated food
Norovirus	Virus	Contaminated food Contaminated liquids Hard surfaces Contact with infected person
Salmonella	Bacteria	Contaminated food Contaminated water Contact with infected animals

The produce commodity group (which includes fruits and vegetables covered under the proposed rule) attributed to 66 percent of viral, 32 percent of bacterial, 25 percent of chemical, and 30 percent of parasitic foodborne illnesses from 1998-2008 (Painter et al., 2013). Leafy vegetables accounted for a greater proportion of foodborne illnesses than the land animal or aquatic animal commodity groups for the following microorganisms: enterotoxogenic *E. coli*, STEC, *Salmonella*,

and Norovirus. Additionally, more foodborne illnesses were attributed to leafy vegetables (22 percent) than to any other commodity group. Painter's study further found that foodborne illnesses associated with leafy vegetables were the second most frequent cause of hospitalizations at 14 percent during the 1998-2008 time period. According to the study, "Previous studies have shown that produce containing foods were the source for approximately half of Norovirus outbreaks with an identified simple food vehicle during 2001–2008 and the second most frequent food source for *E. coli* O157 outbreaks during 1982–2002" (Painter et al., 2013). Outbreaks of STEC infections transmitted by spinach and lettuce, and *Salmonella* infections transmitted by tomatoes, mangos, sprouts, and peppers heighten concerns about contamination of produce that is consumed raw.

Transport of Pathogens in an Agricultural Setting

FDA conducted a qualitative assessment of risk associated with growing, harvesting, packing, and holding of produce and published a draft report on the findings of this assessment as part of the supporting material to the 2013 proposed rule (2013c) (hereinafter referred to as the Draft Qualitative Assessment of Risk or Draft QAR). The Draft QAR provides a scientific evaluation of potential adverse health effects resulting from human exposure to hazards in produce, with a focus on public health risk associated with on-farm microbial contamination of produce. The Draft QAR includes (1) Hazard Identification, (2) Hazard Characterization, (3) Exposure Assessment, and (4) Risk Characterization. This document helped to inform FDA on the risk management decisions the Congressional mandate directs FDA to make, in part, by focusing on those biological hazards that present a risk of serious adverse health consequences or death to the consumer.

Produce commodities are susceptible to exposure to biological hazards before, during, and after harvest. Although the likelihood of exposure to such hazards varies by commodity and by other factors such as cultivation and production systems, the supply chain infrastructure, and environmental considerations, the sources of potential contamination during growing, harvesting, packing, and holding are common across commodities (FDA, 2013c).

Over the years, FDA has obtained information that provides insight regarding the routes of contamination during growing, harvesting, packing, and holding produce safely on farms. Based on findings of the Draft QAR; observations during inspections, investigations, surveillance activities; and other available information, FDA grouped the possible routes of contamination into five pathways: water, soil amendments, animals, worker health and hygiene, and equipment and buildings (FDA, 2013c). These pathways are depicted in Figure 1.7-1 along with exposure routes that begin with the produce commodity and end with consumers.

Figure 1.7-1. Contaminant sources and pathogenic modes of transport through the agricultural environment.

FDA estimates that 2.7 million foodborne illnesses annually are attributable to produce that would be covered by the 2013 proposed rule (FDA, 2013b), and that the number of foodborne illnesses potentially prevented once a rule is finalized is estimated at 1.57 million per year.[11] This equates to an approximate $930 million saved annually in foodborne illness-related expenditures (benefit). The potential cost of compliance with the rule for all affected farms is estimated at $529.62 million annually (FDA, 2014b).

The Wild Farm Alliance (WFA), with substantial technical input from University of California, Davis (UC Davis), USDA, and the Community Alliance with Family Farmers (CAFF), prepared a detailed graphic (Figure 1.7-2) to better illustrate factors that affect pathogen survival in a farm-ecology setting, as well as to highlight co-management techniques that can help improve food safety.[12]

Figure 1.7-2 depicts several modes of pathogen transport that can be related to most agricultural operations relevant to the PS PR. The illustration key for this graphic is included with this EIS as Appendix A. For the purposes of this EIS, the concept of co-management[13] is important in promoting stewardship on the farm, including protecting water and soil quality and conserving wildlife and ecosystem habitat, while balancing food safety and farm productivity goals. Figure 1.7-2 demonstrates co-management techniques that may be employed alongside pathogen vectors.

Important pathogen vectors that highlight the significance of food safety concerns include contaminated animal waste that may in turn contaminate water sources or fields through direct or indirect application, and animal intrusion vectors. Human vectors that are not shown on this graphic include poor hygiene, poor sanitizing practices, and poor packaging practices.

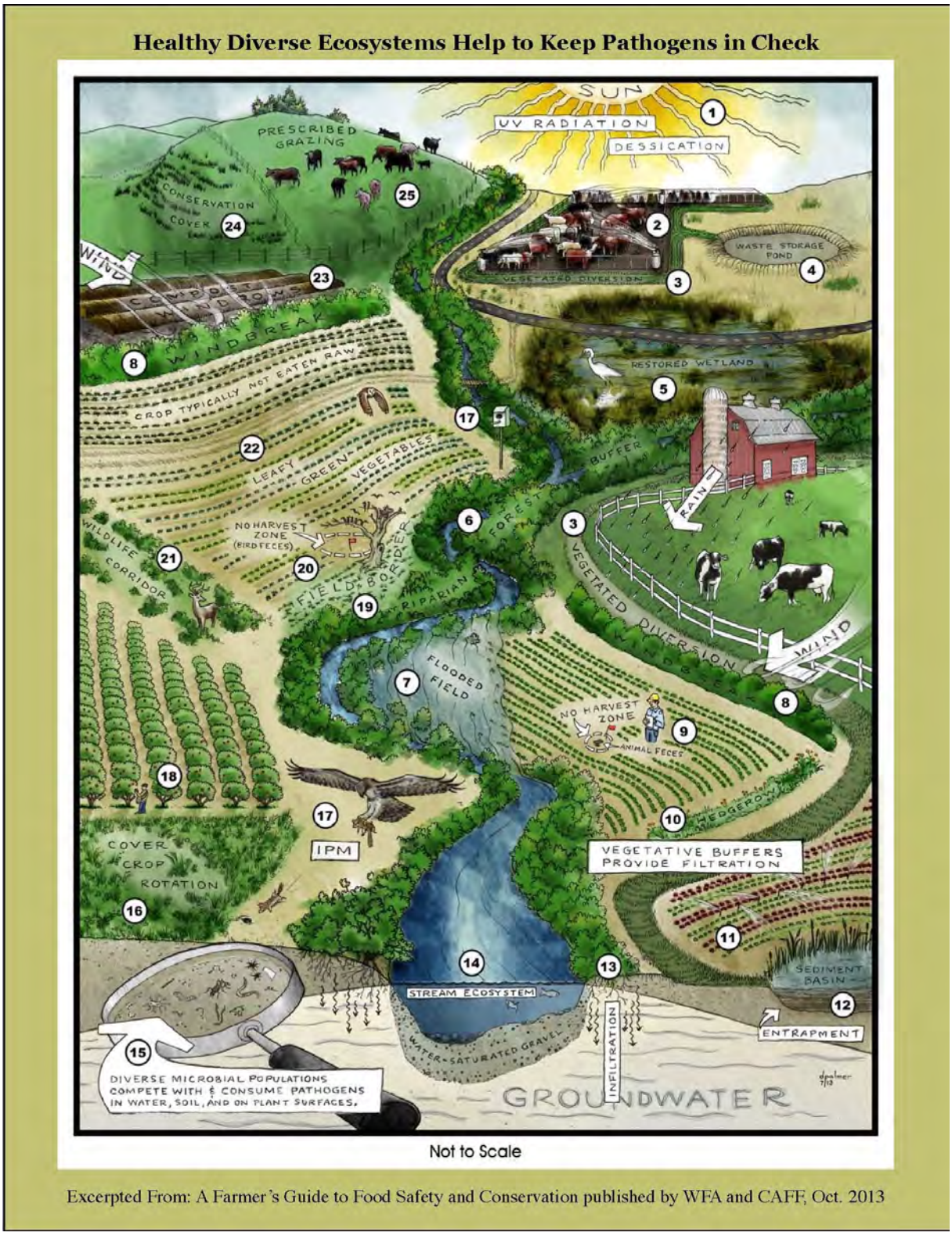
There are many different types of farms, each filling an important role in our nation's food supply chain. The traditional sense of the farm is that it is a source of animal commodities (*e.g.*, beef, pork, fish, or poultry), wheat or grains, or produce. But this would be an oversimplification of what farms yield and the many important benefits that farms have to the local, regional, and national economy. Just as important as what a farm produces is how the land on a farm is used. Farm land and how it is managed has an impact on the local ecology and environment, in addition to its social and economic impact locally and regionally.

[11] Estimate adjusted for changes made in the supplemental proposed rule. Specifically this number does not include the deferred standard for untreated BSAs of animal origin.

[12] The *Healthy, Diverse Ecosystems Help Keep Pathogens in Check* graphic, including *A Farmer's Guide to Food Safety and Conservation*, may be found at http://wildfarmalliance.org/resources/FS_Facts_Tip_FAQ.htm.

[13] Co-management strategies balance food safety concerns with environmental and farm management concerns. The USDA NRCS or local count extension agents offer information and best practices for co-management techniques.

Figure 1.7-2. Basic factors that affect the survival and movement of foodborne pathogens in an agricultural setting



Excerpted From: A Farmer's Guide to Food Safety and Conservation published by WFA and CAFF, Oct. 2013

Farm-to-Table Supply Chain

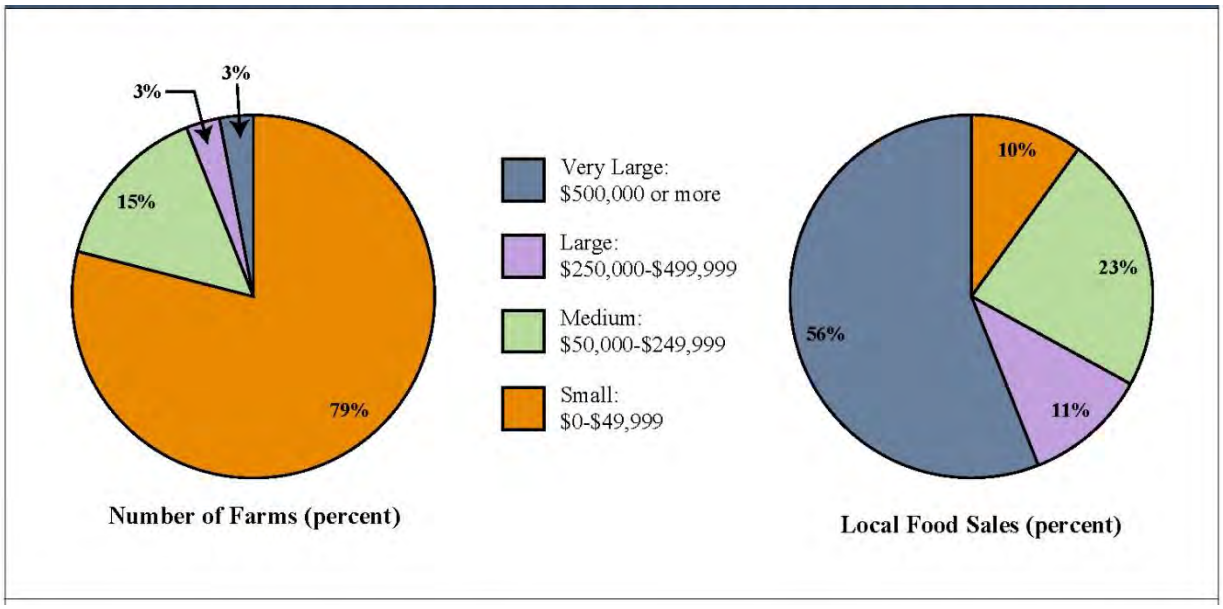
Produce grown in the U.S. originates from farms of all sizes that operate on a local, regional, or national scale. The geographical area that a farm serves depends on factors such as, but not limited to, food production and processing capabilities, the distribution network, food commodity marketing, price of the food commodity, and demand for the food commodity.[14] Growers may not rely solely on their own marketing and distribution system in order to get their food to consumers.[15] Food distribution centers, for example, may purchase food commodities from several growers in a particular area and then process, package, re-brand, and sell those foods together to consumers. Food distribution centers, therefore, may have input in terms of the quality of food products grown and how consistently the food commodities make it to the market, which in turn means that *how* food is grown and harvested may be part of a planning process that involves more than just the farmer (USDA AMS, 2012; USDA AMS, 2013a).[16]

There is a wide variety of produce supply chains that move food commodities to the market places where consumers shop.[17] The example of the food distribution center is valuable in that it demonstrates one model of how food makes it to consumers other than what is commonly perceived as direct sales from farms to consumers, restaurants, or to supermarkets. The opportunities that farmers have to market their food commodities to consumers continue to improve. One result of this more diverse food supply chain is that a greater variety of food is now offered to consumers from a greater variety of growers. Figure 1.7-3 shows the percentage of farms by farm size (in terms of annual revenue) during the years 2008 to 2009 that participate in local food sales to consumers. According to these data, which are provided from USDA's Agricultural Resources Management Survey (conducted annually), "small" farms (*i.e.*, those with local food sales of up to $49,999[18]) make up approximately 79 percent of the participants in local sales but earn ten percent of the total sales. In contrast, under the USDA definition of large farm, large farms make up approximately three percent of the total participants in local sales and earn an estimated 56 percent of the total sales (USDA, 2013).

What this information emphasizes is that farms of all sizes contribute agricultural commodities to local markets, including farms or businesses that also contribute their food commodities to regional or national markets. While this trend is important on many levels to our economy and to farm productivity, it further underscores the need for a reliable food safety system.

[14] USDA operates the Agricultural Marketing Service, which supports domestic production and provides an outlet for surplus food commodities to reach consumers through an approved vendor network all over the nation.
[15] Consumer groups may be made up of individuals, institutions such as schools, restaurants, supermarkets, or others.
[16] More information on the food supply chain may be found at http://www.ams.usda.gov.
[17] USDA works with industry partners to improve farm access to supply chains and regional markets. More information may be found in *Building Regional Produce Supply Chains* (FarmsReach, 2012), and online at www.ers.usda.gov.
[18] Note that the definition of small farms in terms of annual revenue, as used by USDA in this example, is different than the definition of small farm by average annual revenue used by FDA in the PS PR and in this EIS.

Figure 1.7-3. Farms engaged in and the value of local food sales, 2008-2009 average



Source: USDA Agricultural Resources Management Survey 2008-2009 (USDA, 2013)

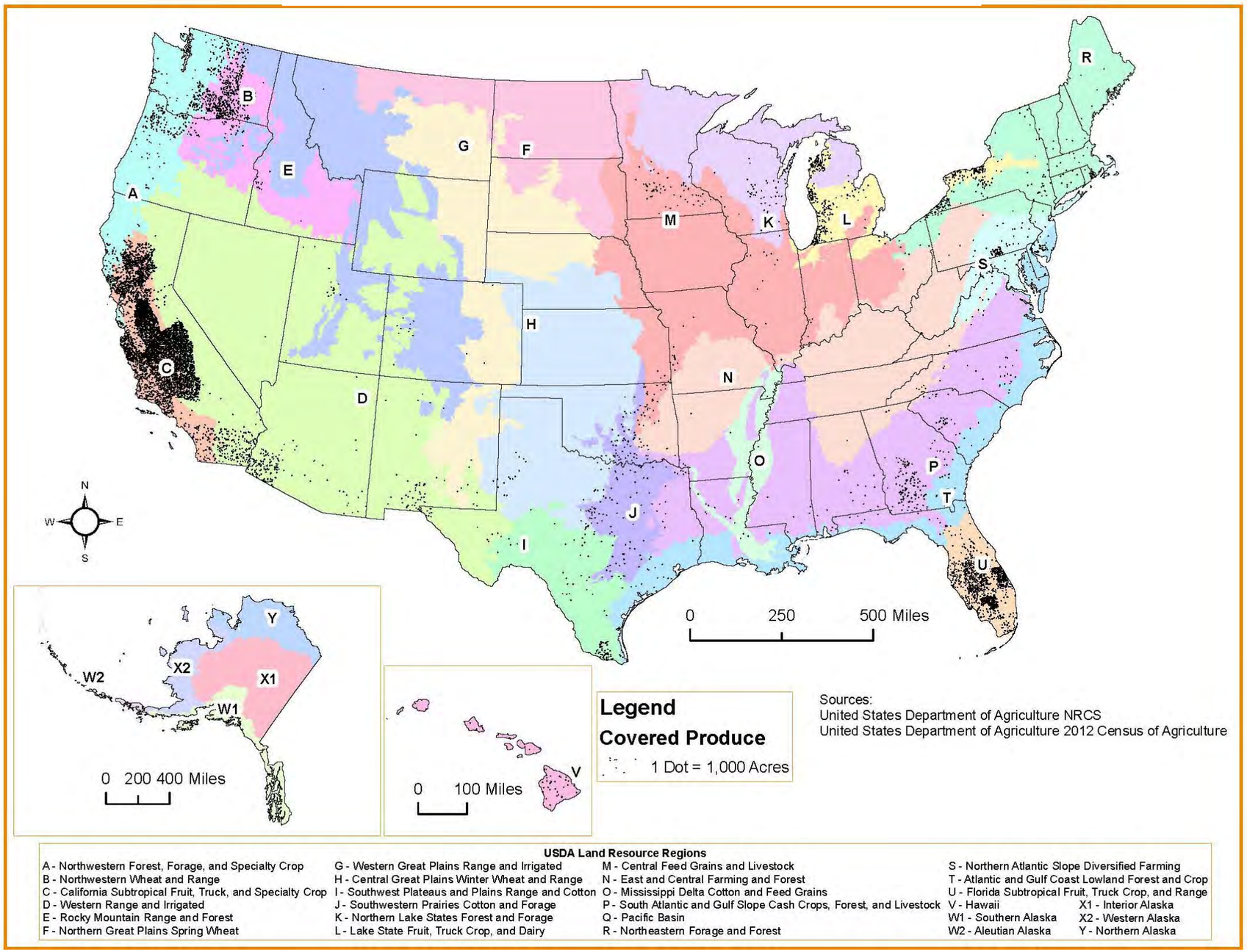
Where covered produce is grown

USDA NRCS developed and maintains a map (as shown in Figure 1.7-4) illustrating 27 Land Resource Regions and Major Land Resource Areas for the U.S. (referred to as "regions" throughout the EIS). The combination of geology, soils, and climate form the foundation for where food is produced. The USDA NRCS subdivided the country into these regions because they share similar soils, climate, and vegetation or crop types (USDA NRCS, 2006).

Figure 1.7-4 serves as a foundation for FDA's analysis within this EIS. The map includes the locations where produce that would be covered by the rule is grown. Data inputs for the map are from USDA's National Agricultural Statistics Service (NASS) 2012 Agricultural Census data (USDA NASS, 2014a).[19] Using this map as a foundation, FDA is able to better compare the relationship between resource components studied in this EIS (*e.g.*, soils and air quality) with common resources such as where BSAs of animal origin are produced, and the availability and quality of water that may be used for irrigation. Of note, Figure 1.7-4 illustrates that high densities of covered produce are grown within Regions B, C, D, L, and U; however, other regions are important as they compare to different resource components studied in the EIS. Produce acreage on the map is represented by dots on the map with each dot representing 1,000 acres of cropland.

[19] More information on the Census of Agriculture may be found at www.agcensus.usda.gov.

Figure 1.7-4. Regions where covered produce in the U.S. is grown



USDA Land Resource Regions

A - Northwestern Forest, Forage, and Specialty Crop	G - Western Great Plains Range and Irrigated	M - Central Feed Grains and Livestock	S - Northern Atlantic Slope Diversified Farming	
B - Northwestern Wheat and Range	H - Central Great Plains Winter Wheat and Range	N - East and Central Farming and Forest	T - Atlantic and Gulf Coast Lowland Forest and Crop	
C - California Subtropical Fruit, Truck, and Specialty Crop	I - Southwest Plateaus and Plains Range and Cotton	O - Mississippi Delta Cotton and Feed Grains	U - Florida Subtropical Fruit, Truck Crop, and Range	
D - Western Range and Irrigated	J - Southwestern Prairies Cotton and Forage	P - South Atlantic and Gulf Slope Cash Crops, Forest, and Livestock	V - Hawaii	X1 - Interior Alaska
E - Rocky Mountain Range and Forest	K - Northern Lake States Forest and Forage	Q - Pacific Basin	W1 - Southern Alaska	X2 - Western Alaska
F - Northern Great Plains Spring Wheat	L - Lake State Fruit, Truck Crop, and Dairy	R - Northeastern Forage and Forest	W2 - Aleutian Alaska	Y - Northern Alaska

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Agricultural management techniques related to the PS PR

Irrigation

Irrigation is the artificial application of water (as opposed to natural rainwater) to land or soil, which is used to support the growing of agricultural commodities (crops). Irrigation systems are used across the world to help augment growing conditions and improve crop yield. Some irrigation systems draw from surface water supplies, and some draw from subsurface sources (groundwater or aquifers) (see Chapter 3.1 Water Resources). Irrigation water may be applied to crops at the soil surface, or at or near the root zone (subsurface). Water quality, including the level and persistence of contaminants or pathogens present in water, is dependent upon many factors that are discussed in Chapter 3 of this EIS. It is generally accepted that water quality is better from subsurface sources (groundwater) as compared to surface water. More information on water quality, sources, water source interactions, and contaminants is presented in Chapter 3.1. In addition, Appendix B offers details on water irrigation systems and applications, and treatment options related to poor water quality conditions.

Biological Soil Amendments

Biological Soil Amendments include organic material such as BSAs of animal origin (*e.g.*, humus, manure, non-fecal animal byproducts such as bone meal or blood meal) and biosolids, which constitute the organic solid product of wastewater treatment processes or sewage sludge; or BSAs of vegetative origin, which includes, but is not limited to, table scraps and yard trimmings. Chapter 3.4 discusses BSAs in greater detail. Appendix C of this document provides an introduction on the application of animal manure, manure management guidance and common handling systems, as well as the methods and timing for manure application, which is helpful to understanding the basis of potential environmental impacts.

1.8 FSMA stakeholder engagement

FDA has participated in an unprecedented level of outreach to producers throughout the U.S. in an effort to hear directly from those who may be most affected by the PS PR.

Since the January 2013 release of the PS PR, FDA has conducted extensive outreach, including conducting more than 100 presentations to industry and consumer groups, farmers, state and local officials, international officials, and the research community. Included in this number are three FDA-sponsored public meetings (District of Columbia; Chicago, Illinois; and Portland, Oregon); six sponsored state meetings (North Carolina, Georgia, Michigan, Ohio, and two in California); numerous other listening sessions accomplished through webinars or in person with stakeholder groups; meetings in Europe with the European Union, the World Trade Organization, and the Global Food Safety Initiative; two extensive U.S. regional farm tours in the Pacific Northwest and in New England; as well as farm tours in Mexico to discuss the combination of the FSMA rules FDA has proposed that, if finalized, would help ensure the safety of both domestic and imported foods. Outreach efforts by the Office of Foods and Veterinary Medicine (OFVM) and program

headquarters staff have been complemented by the outreach of FDA's field and foreign offices, which have also been actively conducting outreach in the various regions where FDA has postings.

Senior FDA staff visited more than 20 farms in 13 states and interfaced with hundreds of stakeholders at various meetings across the country to develop the proposed rule. Many of these meetings included senior officials from the USDA as well as state commissioners of agriculture.

As part of FDA's outreach effort, FDA personnel routinely engaged with the National Association of State Departments of Agriculture (NASDA), the Produce Marketing Association, United Fresh Produce Association, the National Sustainable Agriculture Coalition, the Organic Trade Association as well as with national and regional producer and farm organizations including Western Growers, the American Farm Bureau, the Ohio Produce Growers and Marketers Association and a number of regional produce and fruit and vegetable associations such as the Florida Fruit and Vegetable Association and the California Citrus Growers. FDA personnel also routinely engaged other significant FDA foods stakeholders on produce issues, such as the Safe Food Coalition, the Grocery Manufacturers Association, and the Food Marketing Institute.

In addition, two produce-related alliances were established: the Produce Safety Alliance (PSA) and the Sprout Safety Alliance. The PSA is a collaborative project between Cornell University, USDA, and FDA. The overarching objective of this project is to provide the produce industry and associated groups with training and educational opportunities related to current best practices and guidance, as well as technical assistance on the PS PR. The Sprouts Safety Alliance was created in cooperation with the Illinois Institute of Technology's Institute for Food Safety and Health to assist sprout producers in identifying and implementing best practices in the safe production of sprouts.

FDA posts all information relevant to the PS PR on the FDA FSMA webpage.[20] This webpage includes information specific to farmers such as a produce safety resources toolkit, summary information on produce provisions, an extensive set of questions and answers, as well as blogs, interviews, speeches and PowerPoint presentations on the PS PR. The information posted on the FDA FSMA website is shared through a list serve that has over 20,000 subscribers.

Issues raised during public and agency scoping

In addition to the outreach effort described above, FDA sought comment from the public on a number of environmental issues raised in questions published in the 2013 proposed rule. The agency has evaluated the information and input received in response to the PS PR to determine further actions, as appropriate, when developing this EIS.

Through public involvement, FDA determined a range of issues including potentially significant issues to be addressed in the EIS. This section provides an overview of the scoping process FDA used, including timing, and summarizes comments FDA received during the scoping period, including those received at the scoping meeting.

[20] http://www.fda.gov/Food/GuidanceRegulation/FSMA/.

Scoping – Public Notification

On August 19, 2013, FDA initiated the EIS process by publishing a *Notice of Intent (NOI) to Prepare an Environmental Impact Statement for the Proposed Rule* in the *Federal Register* (78 Fed. Reg. 50358). The NOI provided general information on the 2013 proposed rule and announced the beginning of the scoping process, the period during which FDA and the public collaborate to identify issues to be addressed in the EIS. Specifically, the NOI invited the public to submit comments for FDA's consideration during the preparation of the EIS and to aid FDA with determining the need to hold any public scoping meetings. FDA stated that it would receive such comments until the closing date, November 22, 2013.

Subsequently, FDA announced a comment period extension for the EIS on the PS PR that extended the comment period to March 15, 2014 (78 Fed. Reg. 69006, November 18, 2013). The extension was provided to allow interested parties more time to provide comments on the scope and significance of issues that FDA should consider in the EIS. The extension was also granted to allow FDA additional time to hold, as appropriate, one or more public scoping meetings.

On March 11, 2014, FDA announced a public scoping meeting on the EIS for April 4, 2014, in College Park, Maryland, and a second comment period extension for the EIS that extended the comment period from March 15, 2014, to April 18, 2014 (79 Fed. Reg. 13593). The comment period for the scope of the EIS ended on April 18, 2014. In addition to providing information on the proposed rule, the March 11, 2014, *Federal Register* publication announcing the public scoping meeting further included a summary (based on FDA's preliminary review of comments, currently available information, and further analysis of the 2013 proposed rule) of those provisions of the proposed rule that may significantly affect the quality of the human environment, and a range of potential alternatives for each provision for consideration in the EIS. FDA requested public comment on specific issues, alternatives, mitigation measures, or other information FDA should include for further analysis in the EIS.

Scoping – Public Outreach and Involvement

During the full scoping period for the EIS on the proposed rule (August 19, 2013, through April 18, 2014), FDA provided numerous ways that the public could participate in the EIS process. For example, the above-mentioned notices in the *Federal Register* provided instructions for submitting comments electronically via the Federal eRulemaking Portal at http://www.regulations.gov or by mail/hand delivery/courier (for paper or CD-ROM submissions).

The public scoping meeting was held on April 4, 2014, at the Harvey W. Wiley Federal Building Auditorium in College Park, Maryland, from 1 p.m. – 5 p.m. (EST). Public participants had the option of attending the meeting in person or via an interactive live webcast, and a recording of the webcast was made available after the meeting.[21] The scoping meeting included a session that allowed individuals to review posters describing the issues under consideration for the EIS. During

[21] The full transcripts and recording of the meeting are available at http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm388369.htm.

the poster session, FDA staff was on hand to answer questions and discuss poster content. The meeting included a presentation by FDA on the background of the PS PR and the scoping process, an overview of the NEPA process, proposed alternatives for provisions of the proposed rule that may significantly impact the quality of the human environment, and how the public may submit comment on the scope of the EIS. The scoping meeting also had an open microphone session where attendees were offered opportunities to provide comments, followed by a question and answer (Q&A) session between the audience and FDA officials. A court reporter was also available on-site throughout the entire meeting to transcribe oral comments.

FDA received more than 36,000 comments to the rulemaking docket. This includes comments received on the 2013 proposed rule and the supplemental proposed rule, as well as comments received in response to public involvement for the EIS. In the 2013 proposed rule, FDA stated that we were seeking comments on the potential environmental effects as part of the public comment period, including specific comments regarding agricultural water, BSAs of animal origin, and wildlife. FDA stated, in the August 19, 2013, EIS NOI, that these comments are still relevant to the environmental analysis. Consequently, FDA reviewed these comments on environmental issues in response to the 2013 proposed rule and supplemental proposed rule along with comments received as part of the EIS scoping process, in addition to other data and information, to determine the specific issues and alternatives FDA should include for analysis in the EIS.

Scoping – Agency Involvement, Consultation, and Cooperation

Pursuant to 40 CFR 1501.7(a)(1), as the lead agency, FDA is required to "invite the participation of affected Federal, State, and local agencies, any affected Indian tribe, the proponent of the action, and other interested persons (including those who might not be in accord with the action on environmental grounds)."

According to 40 CFR 1508.5, a "cooperating agency" is "any Federal agency other than a lead agency which has jurisdiction by law or special expertise with respect to any environmental impact involved in a proposal (or a reasonable alternative) for legislation or other major Federal action significantly affecting the quality of the human environment." In August of 2013, FDA sent letters to EPA, USDA, and the USFWS requesting their participation as cooperating agencies in the preparation of the EIS. At that time, FDA also sent letters to the State Departments of Agriculture inviting their comments to the docket and providing them the opportunity to request cooperating agency status, although not issuing a formal invitation.

USDA agreed to be an official cooperating agency, which entailed providing technical comments on the scoping of the EIS, the technical approach to the EIS, and a draft of the EIS. These comments were considered by FDA along with those received through stakeholder engagement during the scoping period, relevant stakeholder comments on the PS PR, and input received from other federal agencies. USDA did not review the Final EIS prior to publication. Within USDA, FDA has consulted with USDA AMS, which oversees the organic program; and NRCS, which develops and maintains the National Conservation Practice Standards. In addition, EPA has answered questions from FDA on an as-requested basis and has responded to requests for formal opinions on various topics of the PS PR. The USFWS has also agreed to work with FDA through

other appropriate channels, specifically with regards to the ESA. Having these agencies involved helped to ensure that environmental and conservation standards and policies established by these agencies were appropriately considered in developing the EIS.

For a summary of tribal outreach on the EIS for the PS PR as well as information on which tribes specifically requested consultation with FDA, please see the Tribal Outreach section directly following Table 1.8-1 below.

Scoping – Summary of Comments

Comments received with respect to the PS PR and during the EIS scoping period were generally grouped by resource component assessed for environmental impact analysis. Table 1.8-1 summarizes the comments raised by the public from the oral statements and written comments received and generally identifies the sections of this Final EIS where we considered these comments. These comments provide a general summary of comments submitted that relate to the scope of the EIS. It is important to note that FDA has addressed some of the concerns of these comments by proposing to amend some specific provisions and proposing new provisions within the supplemental proposed rule.

Table 1.8-1. Summary of comments identified for inclusion in the scope of the EIS

Comments/Issues		Sections of EIS where comments are considered in evaluating environmental impacts
Water Resources	Concern that the proposed rule would create a preference for synthetic fertilizers which would increase groundwater nitrate which could cause future environmental effects such as eutrophication downstream. Increased use of synthetic fertilizers can cause agricultural runoff and pollution.	Potential impacts are addressed in Chapter 4.3, subpart F
	Concern that the proposed rule creates a preference for farmers to use groundwater, municipal water, and/or public water. Switching to municipal water could place an increased demand on already-stressed municipal water supplies. Switching from surface water to groundwater/municipal/public water could put significant pressure on water supplies and aquatic ecosystems. Using municipal water could decrease minimum flows, thereby harming aquatic life.	Potential impacts are addressed in Chapter 4.2, subpart E
	Concern over treatment residue from chemicals used to treat surface water. Encourage FDA to look at which chemicals farmers will likely use to treat surface water. Residue from treatment could impact water resources and aquatic animals because of agricultural runoff and leachate containing chemically treated irrigation water. Tailwater resulting from using treated irrigation water may negatively impact aquatic life.	Potential impacts are addressed in Chapter 4.2, subpart E

Comments/Issues		Sections of EIS where comments are considered in evaluating environmental impacts
	EPA's 1986 Recreational Water Standard is not flexible/risk-based enough because it applies regardless of risk, climate, location, farming system, or water system. In many parts of the country, surface water cannot meet this standard without chemical water treatment. The proposed rule creates a preference for chemical water treatment.	FDA proposed amended provisions in the supplemental proposed rule, and the EIS addresses added flexibility of these provisions in Chapter 2.1.
	Need to examine unique irrigation challenges that exist in various parts of the country.	Chapter 1.9 addresses the EIS scope; potential impacts are found in Chapter 4.2 subpart E; and Appendix B discusses irrigation practices.
Biological and Ecological Resources	Concern over impacts on non-target wildlife from methods used to control pests and wildlife, such as habitat removal, fencing, and poison. Special concern over harming migratory birds and threatened and endangered species. Food safety and conservation should be co-managed.	Chapter 2.1 subpart I, Chapter 4.5 subpart I.
	To avoid the proposed rule's animal monitoring requirements, farmers may take actions such as habitat destruction and clearing farm borders.	FDA proposed new provisions in the supplemental proposed rule, and the EIS addresses this issue in Chapter 2.1 subpart I, and Chapter 4.
Soils	Adopt soil treatment regulations (relative to BSAs) that align with USDA organic regulations.	BSAs of animal origin, relative to potential future regulation and interaction with USDA's organic regulations are addressed in Chapter 1.4, Chapter 2.1 subpart F, and Chapter 4.3 subpart F
	Unspecified concerns about the natural biological integrity of the soil (soil quality) as a result of changes in BSA practices.	Chapter 4.3 and 4.4 subpart F
	Manure management rules could impact manure use. Animal waste (manure) returns nutrients to the soil contributing to healthy soil life.	Chapter 4.3 subpart F
Waste Generation, Disposal, and Resource Use	Proposed rule does not address Concentrated Animal Feeding Operations (CAFOs), use of which could increase due to restrictions on animal grazing and result in increased raw manure generation and subsequent impacts to soil and water quality.	Chapter 3.4 and Chapter 4.3 subpart F
	Concern over application intervals in some parts of the country being longer than the growing season, resulting in a switch to non-produce crops or lower yields for crops produced in those areas.	Chapter 4.3 and 4.4 subpart F

Comments/Issues		Sections of EIS where comments are considered in evaluating environmental impacts
	Concern that the proposed rule could deter farmers from using manure causing stockpiles to form.	Chapter 4.3 subpart F
	Concern that the proposed rule creates a preference for farmers to use synthetic fertilizers, resulting in increased environmental exposures, as opposed to biological soil amendments.	Chapter 4.3 and 4.4 subpart F
Air Quality	Concern about impacts on air quality from water purification processes.	Chapter 4.2 subpart E
	Concern over impacts on energy usage to treat and/or store water: Increased energy could involve emissions affecting farmers' ability to meet Clean Air Act/Greenhouse gas reduction standards.	Chapter 4.2 subpart E
	Concern that the proposed rule creates a preference for synthetic fertilizers over biological soil amendments—could lead to additional emissions and energy expenditure to produce the synthetics. Synthetic fertilizers can cause air impacts due to the formation and release of the greenhouse gas nitrous oxide (N_2O) when there are high concentrations of soluble nitrogen present in the soil.	Chapter 4.3 and 4.4 subpart E
	Concern over increased transportation emissions to get rid of untreated animal waste and/or import of synthetic fertilizers or treated amendments.	Chapter 4.3 subpart F
	Concern over anaerobic decay of large concentrations of wastes (both raw manure and composting).	Chapter 4.3 subpart E
Cultural Resources	Concern over the end/decline of farming as a way of life. Concern that the proposed rule will discourage traditional agricultural practices and/or the growing of traditional cultural crops.	Chapter 3.6.1

Comments/Issues		Sections of EIS where comments are considered in evaluating environmental impacts
Socioeconomics & Environmental Justice (including Tribal Resources)	Concern about environmental impacts stemming from small farms going out of business due to costs associated with complying with the proposed rule.	Chapter 4.2 and 4.7
	With many tribes being located in arid regions, tribes have expressed concern that the proposed rule's water quality standards could cause an increase in groundwater demand and exacerbate water rights concerns.	Chapter 4.2 subpart E
	Concern about tribes' access to local produce, especially in light of the prevalence of significant medical conditions among tribal populations.	Chapter 4 subpart E as it relates to all disadvantaged or low income populations.
	Concern that the proposed rule, in aggregate, may have a disproportionate impact on minority, low-income, and the socially disadvantaged.	Chapter 4
	Concern that the proposed rule creates incentives for mono-culture and conventional farming over diversified farms.	Chapter 4.2 subpart E
	Concern that proposed rule will raise prices of locally grown food causing consumers with lower incomes to be unable to afford them.	Chapter 4.2 subpart E
Human Health and Safety	Concern over access to fresh/local/organic food because the proposed rule could create a preference for factory/commercial/mass-produced food farms that use genetically modified organisms (GMOs) or CAFOs.	Chapter 4.2 subpart E
	Several supportive comments on provisions that improve measures to protect public health.	Chapter 4
	Concern that the proposed rule does not go far enough to protect public health. This is demonstrated by the fact that some existing industry marketing agreements have more stringent standards with respect to BSAs than do the provisions of the PS PR.	Chapter 4

Scoping – Tribal Outreach

The FDA has been in consultation with several interested Native American Indian Tribes since we sent the invitation for consultation on the EIS in August 2013. A timeline showing the record of outreach and communication between FDA and interested tribal parties appears in Appendix D. Appendix D also includes a list of Native American Indian Tribes that are located within the ten HHS Regions and that have expressed interest in food safety to FDA (HHS, 2014). Chapter 3.7 provides a greater discussion of the affected environment for Native American Indian Tribes. A full list of all 566 federally recognized tribes can be found at 79 Fed. Reg. 4748 (January 29, 2014).

Draft EIS

In accordance with 40 CFR 1503.1, FDA requested and obtained comments on the Draft EIS from other federal agencies with jurisdiction by law or special expertise in environmental standards, appropriate state and local agencies, sovereign Tribes, the regulatory community, and the public. The Draft EIS was published on FDA's Web site on January 12, 2015. The Notice of Availability (NOA) for the Draft EIS was published in the *Federal Register* on January 14, 2015 (80 Fed. Reg. 1852). On February 10, 2015, FDA held a public meeting where presenters provided public testimony. The meeting was broadcast via webcast and open to participants nationwide, and comments to the Docket were obtained during the comment period. The comment period closed on March 13, 2015.

FDA received 30 comments on the Draft EIS from interested parties, industry groups, consumer groups, and a Native American Indian Tribe. USDA, in fulfilling its responsibilities as a cooperating agency in accordance with 40 CFR 1501.6, submitted feedback and input on the Draft EIS. FDA incorporated USDA's edits when preparing the Final EIS. EPA submitted its review of the Draft EIS in accordance with EPA's authorities under NEPA and Section 309 of the Clean Air Act (see Appendix F). FDA considered each comment. Many of the comments addressed specific potentially significant provisions and the environmental impact analysis conducted in Chapter 4 of the EIS. Some comments addressed concerns about the NEPA process. Others expressed concern that the EIS did not conduct a more detailed impact analysis at a more localized geography.

FDA also received comments that addressed the scope and purpose of the rule, including comments that were generally supportive of the PS PR as well as comments that questioned the scientific or technical rationale for specific proposed requirements or asked for clarification about the proposed requirements. These comments were added to the docket for the PS PR and considered in developing the final rule. In addition, we received comments that address topics unrelated to the EIS, *e.g.*, requests for FDA to consider developing new pathogen detection methods, requests for clarification on what was considered when developing the proposed rule, or statements that expertise is available for compliance and enforcement actions. Such comments are not related to the EIS and we do not address them in this document.

We respond to the substantive comments (those that raise substantial or meaningful issues regarding the Draft EIS) in accordance with 40 CFR 1502.3 in Appendix E. Some commenters included discussion of multiple, discrete issues. FDA identified within our response to comments where changes were made within the body of the Final EIS, as appropriate. Although some commenters did recommend additional alternatives for analysis in the Final EIS, FDA considered these recommendations but did not find the suggested alternatives to reasonably meet the purpose and need for the proposed action; therefore, we did not assess any new alternatives in the Final EIS. Our consideration of those comments and the reasoning behind FDA's decision to not further analyze the recommended alternatives is described in Chapter 2.2 and also in Appendix E, in response to those comments.

1.9 Scope of the EIS

In the discussion of the scope of the Draft EIS (Chapter 1.9), we identified a number of factors that could influence a grower's management decision in response to the requirements in a produce safety final rule. The factors included the availability of "safe" water or an alternative "safe" water supply (including the ability to apply flexibility options provided in the PS PR), costs associated with accessing the water, availability and costs associated with soil amendments, the extent to which grazing animals or wildlife may contaminate covered produce, climate and weather, soil quality conditions, topography, demand and prices for certain agricultural commodities, and the type of crop being grown. We stated that these factors vary widely across the nation and may not be the same among neighboring farms (id). We determined it was not feasible for an EIS to assess individual (site-specific) potential environmental variables (id). Data and information are not available concerning these local conditions affecting specific individual growers. Instead, we relied on a geographic framework at a regional and national level for our analysis in this EIS, focusing our analysis on those regions where covered produce is grown. Where possible, we also considered environmental impacts at a state level when data and information were available.

The comments we received on this approach asserted that we should have assessed environmental effects on a more localized scale. We disagree (see response to the comment summary under the heading "Scope of the EIS: Analysis of Localized/Regional Impacts" in Appendix E). This EIS is being prepared in response to an urgent public health need to establish and implement FDA produce safety minimum science-based standards to, in part, to minimize the risk of serious adverse health consequences or death from contaminated produce. Produce-related foodborne illness outbreaks are a serious and ongoing safety problem. In fact, the history of produce-related outbreaks was the impetus for Congress, in FSMA, to require federal produce safety standards that are focused on prevention and for which FDA is under statutory timeframes to complete. Implementation of the produce safety standards by covered farms engaged in the growing, harvesting, packing, and/or holding of produce is critical to reducing foodborne illness from contaminated produce.

It is against this backdrop that we balanced the cost of any uncertainty with respect to local environmental impacts with the need to complete the final rule. The cost in time and resources of attempting to obtain the data and information for thousands of covered farms to assess local environmental impacts through, for example, a market survey of covered farms subject to the final rule would be unwieldy, impracticable, and likely not helpful considering that local conditions are ever changing. It would likely take months, if not years, to develop surveys, identify covered farms, gather and decipher responses received, conduct a statistical analysis, and evaluate information that may no longer be accurate due to changing conditions from initiation to completion of any such survey. Nor would this lengthy process be feasible or appropriate to meet the need to implement produce safety standards as expediently as possible.

We relied on the best and currently available data from USDA, EPA, and USGS from which we could determine which regions may be most impacted. Moreover, we relied on a statistical analysis conducted using a USDA NASS Fruit and Vegetable Agricultural Practices Survey (USDA NASS, 2001), and the most recent agricultural statistics survey (USDA NASS, 2014a) for information on

potentially affected produce growing farms as a data source. In addition, FDA through USDA asked a series of questions of the state departments of agriculture to assist in supplying any available data. The data used to make our impact assessment in the Draft and this Final EIS at a national and regional scale are based on the best available information. Moreover, our decision to structure our analysis at a national, regional, and where possible, state level, is reasonable and within our discretion under NEPA (see 40 CFR 1504.2(b) and (c)).

As discussed in Chapter 1.5, FDA determined that microbiological hazards pose the greatest risk of serious adverse health consequences or death. FDA prepared its Draft QAR associated with growing, harvesting, packing, and holding of produce. In particular, the Draft QAR was intended to address various risk management questions related to biological hazards of concern in fresh produce that can lead to serious adverse health consequences or death, potential routes of contamination, and the likelihood of contamination and likelihood of illness attributable to consumption among various types of produce commodities. The findings of the Draft QAR informed FDA's regulatory approach and several proposed provisions[22] (see Chapter 1.4 for proposed provisions).

FDA determined that the PS PR contains four potentially significant provisions that, if finalized, may significantly affect the quality of the human environment: (subpart E) Standards directed to agricultural water, (subpart F) Standards directed to BSAs of animal origin and human waste, (subpart I) Standards directed to domesticated and wild animals, and (subpart A) General provisions (under which the combined impacts of the PS PR are considered if the farm is covered under subpart A). These potentially significant provisions form the foundation for our environmental impact analysis in Chapter 4.

There are management decisions related to compliance with these potentially significant provisions that a grower may make that may result in environmental effects that may significantly impact the human environment, and include effects which may be later in time or farther removed in distance, but are still reasonably foreseeable (40 CFR 1508.8). For example, if agricultural water is unsafe for use, then the grower may make a management decision that may include treating the water source, changing the irrigation mechanism, changing the water source, ceasing to grow covered produce, or adding a post-harvest rinse to account for microbial removal. Chapter 4 addresses the potential effects of the potentially significant provisions along with proposed alternatives. Alternatives for each such provision are identified in Chapter 2.1. FDA also recognizes that proposed provisions of the PS PR, taken together and taken with other reasonably foreseeable federal or state actions, may result in significant cumulative effects. These potential cumulative effects are addressed in Chapter 5.

FDA used a qualitative approach in assessing potential environmental impacts in this Final EIS that is consistent with the 2014 CEQ guidance, *Effective Use of Programmatic NEPA Reviews* (CEQ, 2014a). CEQ provides that a NEPA analysis may be on a site- or project-specific level, or on a broader, programmatic level. Programmatic analyses set out a broad view of environmental impacts or benefits. FDA addresses impacts on a national, regional, and where possible, state level

[22] A summary of the Draft QAR is found in Section IV(A) of the 2013 proposed rule (78 Fed. Reg. 3504 at 3522).

when we evaluate the covered farms that may be subject to certain provisions of the rule, *e.g.*, subpart F Untreated BSAs of animal origin (*e.g.*, Chapter 2.1 Tables 2.1-3 and 2.1-4). For most resource components evaluated in this EIS, background environmental conditions and data are available to help establish the foundation for potential environmental impacts with respect to the proposed action for covered produce, by region. However, for certain resource components, *e.g.*, certain aspects of water resources and socioeconomics and environmental justice, sufficient data are available to determine environmental impacts at the state level.

With respect to Socioeconomic Impacts and Environmental Justice, FDA considers the potential impacts to minority principal farm operators and farmworkers. USDA NASS survey data provide information on principal operators of farms. The USDA ERS, U.S. Department of Labor (DOL), and the Bureau of Economic Analysis (BEA) provide data on farm employment (see Chapter 3.7.3). The USDA NASS survey data provide some information on farmworker income levels. The DOL reports some data on farmworkers in terms of ethnicity and income (see also Chapter 3.7.3). Farmworker employment may be dependent upon multiple factors including (but not limited to) average annual farm income, estimates for crop yield, and commodity prices. Increases in farm operating costs may also impact farmworker employment. It should be noted that farmworker employment can be highly seasonal (USDA Economic Research Service (ERS), 2014a). The background information for principal operators and farmworkers that fall within this resource component is in Chapter 3.7.

FDA received public comment on the Draft EIS that expressed concern that the EIS does not assess costs to consumers. FDA addressed costs of the PS PR (including to consumers) in its 2013 preliminary regulatory impact analysis (PRIA) (FDA, 2013a) and the supplemental PRIA (FDA, 2014b). FDA examined economic impacts of the PS PR in accordance with Executive Orders 13563 and 12866. We refer you to that analysis for further information.

Geographical scope

As discussed in Chapter 1.6, FDA proposes to cover produce commodities, with some exemptions, within the scope of the PS PR. These produce that are covered by the rule are considered "covered produce." Covered produce grown within the 50 states is shown on Figure 1.7-4. The scope of this EIS includes the conterminous U.S., Alaska, Hawaii, and the EIS geographical areas. To the extent any environmental impacts stem from activities taken in response to the rule, if finalized, in areas within the geographical scope of the EIS, such transboundary impacts[23] are also part of our analysis.

Conterminous U.S., Alaska and Hawaii

Most information important for conducting an impact analysis relates to produce farming activities within the 50 states. There are more data available for certain states, such as California, where more than 80 percent of produce that would be covered by the rule is grown. Wherever possible, potential impacts are discussed by state, but impacts are generally assessed by region or

[23] Transboundary effects, as discussed here, are those that cross borders with other countries (*i.e.*, Canada and Mexico).

nationwide. A major source for information on where produce commodities are grown is compiled through USDA NASS 2012 surveys (see Chapter 1.7).

As described in Chapter 3, the data and information concerning current farming practices for covered produce and the environmental impacts of such practices vary for each resource component. For example, Chapter 3.1 Water Resources draws on information on water contamination published in nationwide databases that are managed by the U.S. Geological Survey (USGS) and EPA. For most resource components, background environmental conditions and data are available to help establish the foundation for potential environmental impacts with respect to the proposed action for covered produce, by region. For certain resource components (certain aspects of water resources and socioeconomics and environmental justice) there are enough data available to determine environmental impacts by state.

EIS Geographical Areas

The 2012 Census of Agriculture did not include data on any region in the EIS geographic areas (Puerto Rico, U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands) except for Puerto Rico.[24] FDA included Puerto Rico within its estimates for covered farms in the 2013 PRIA and supplemental PRIA (FDA, 2013b and 2014b, respectively), so estimates throughout the EIS of the total number of covered farms, acreage and cost include Puerto Rico. For this EIS, FDA reviewed the 2007 USDA NASS survey data for American Samoa, Guam, Northern Mariana Islands, and the U.S. Virgin Islands, as USDA did not publish surveyed data for these regions in 2012 (USDA NASS, 2011; USDA NASS, 2009a,b,c):[25]

- Guam: There are 104 total farms with an average farm size of 9.6 acres per farm. The average estimated revenue for fruit commodity farms was reported at about $7,000, and the average estimated annual revenue of fruit and vegetable farms was reported at just over $18,000 per farm.
- American Samoa: There are 5,840 total farms. The average annual revenue for fruit, nut, and vegetable crops is less than $10,000, and sales are generally reported as $500 or more.
- Northern Mariana Islands: There are 256 total farms. Produce farms reported an average of less than three acres per farm with average annual estimated revenue of less than $6,000 per farm.
- U.S. Virgin Islands: There are 219 total farms reporting an average of 27 acres per farm. The estimated average annual revenue of produce farms is less than $4,000 per farm.

Because the estimated average annual revenue reported for the EIS geographical areas is below the proposed $25,000 threshold for the value of produce sold for farms to be "covered" by the rule, it appears that most produce farms in the EIS geographical areas would be excluded from the PS PR (proposed 21 CFR 112.4). In addition, limited other environmental background information (not related specifically to agriculture) is available for water quality and air quality for some of

[24] Note that Puerto Rico, is included within the count for covered farms, and within Chapter 3.7 as socioeconomic information was available for Puerto Rico, but it is not included on EIS maps showing where covered produce is grown.

[25] The type of data available by U.S. Territory varied based on what was reported. The total number of farms reported here by Territory includes produce and non-produce farms.

these areas. Therefore, because most farms within these areas may be excluded from the rule, environmental impacts from any changed farming practices would not be significant. Therefore, no EIS geographical area except Puerto Rico is included within the analysis of this EIS.

Regarding environmental resources that are shared transboundary and the information we have on such resources (*e.g.*, aquifers), we relied on reports and information prepared by the Texas A&M University (Eckstein, 2011), USGS (2010 and 2013a), and the Congressional Research Service (Carter et al., 2015).

International Growers

A portion of the covered produce consumed domestically is grown in foreign countries. The provisions of the PS PR, if finalized, would apply to both domestic and imported produce. FDA intends to evaluate its obligations with Executive Order (EO) 12114, "Environmental Effects Abroad of Major Federal Actions," related to this action in a document that is separate from this EIS.

Time scope

This section establishes a timeframe within which reasonably foreseeable effects (impacts) from implementation of a final rule may begin occurring. The provisions of the PS PR, if finalized, would occur in accordance with proposed compliance dates, as follows:[26]

- Very small businesses, those with more than $25,000 but no more than $250,000 in annual produce sales, would have four years after the rule's effective date to comply with most provisions;
- Small businesses, those with more than $250,000 but no more than $500,000 in produce sales, would have three years after the rule's effective date to comply with most provisions;
- All other farms would have two years after the effective date to comply with most provisions; and,
- The compliance dates for water quality standards and related testing and recordkeeping provisions would be an additional two years beyond the compliance dates listed above for very small, small, and all other farms.

Additional corresponding pressures on agricultural producers

The U.S. Census of Agriculture reports that 914.5 million acres of land in the U.S., including the 50 states and Puerto Rico, were farmed in 2012. The amount of land farmed has declined in every agricultural census since 1982, when 986.8 million acres of land were farmed. Since 1982, farmland acreage has declined 7.3 percent overall. Analysis of trends between 1997 and 2002 and between 2002 and 2007 shows a decrease in the amount of land farmed of 1.7 percent within each five-year period. Analysis of the trend between 2007 and 2012 shows a decelerating rate (compared to the rates from 1997 to 2007) of decrease in the amount of land farmed of 0.8 percent (USDA NASS, 1982 to 2012 surveys). Additionally, trend analysis as demonstrated in Chapter 3.7 shows that the average age of principal operators (farmers) is increasing, and fewer people are

[26] Information on compliance dates is found on FDA's Web site: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm.

entering the profession, which presents an overall ongoing decline in farming. It is unclear what the current land that was previously used for farming is currently being used for: for example, whether the land is currently in reserve (left to go fallow, or unused to avoid surplus production), whether the land has been transferred to residential development, whether the land is being managed in some other way, or a combination of these or other factors.

Climate change is anticipated to have a continued impact on farming and food security. The recent report released by the Intergovernmental Panel on Climate Change (IPCC) demonstrates that some regions within our geographical scope may continue to experience drought conditions, precipitation variability and temperature extremes, particularly in semi-arid regions (West) of North America (IPPC, 2014). Even despite climate change, the trends associated with drought conditions, particularly in Western states, has resulted in conditions that include but are not limited to a rise in water prices, shifts in commodities that make more money (*e.g.*, almonds), adapting or switching irrigation systems and sources in response to low-rainfall conditions, decline in agricultural-related employment, and preserving water resources (water banking) to improve water conservation. A recent study by University of California, Davis shows that as many as 17,100 jobs have been lost in California, state-wide, related to drought conditions (Howitt et al., 2014). The University also reports that California farms (not just farms growing produce that would be covered by the rule) have abandoned or let go fallow up to 500,000 acres of agricultural land this year; simultaneously, more growers are switching to drip irrigation systems as a means to reduce water use.

Pests and disease continue to burden farms, crop yields, and the ability of the grower to efficiently and sustainably farm the land. For example, the recent "orange greening" scourge in Florida has affected nearly every orange grove in the state, which directly impacts crop yields and, subsequently, prices of commodities (USDA ARS, 2014).

Growers of produce adapt to changing conditions in the market and the environment. The changing agricultural landscape has contributed to an overall decline in domestic agricultural production, as well as a decline in the number of principal operators (trends in farming including those that demonstrate a decline in farming by operator type, farm tenure, and age of operators are discussed in Chapter 3.7.3). Irrespective of any final rule, current trends in the decline of domestic agricultural production are anticipated to continue. Several programs exist today to help farmers incorporate food safety into their growing practices and adapt to economic conditions, drought and other climate effects, pests and disease, and other pressures. This includes a network of partnerships between farmers and Government and industry, such as the following:

- FDA for a hundred years has had the responsibility to prevent foods from being contaminated and to set standards for labeling foods to help people know what they are buying and to choose healthy diets. In 1998, FDA issued its *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* (hereinafter referred to as the "1998 Guide" or "FDA's 1998 Guide") (FDA, 1998).[27] In 2002, the New

[27] Since the document was issued as guidance and not as a regulation, it does not have the force and effect of law and therefore does not contain enforceable requirements (FDA, 1998).

Jersey Department of Agriculture petitioned USDA AMS to implement an audit-based program to verify conformance with the 1998 Guide. This led to the creation of USDA AMS's GAP and Good Handling Practices (GHP) audit verification program, known collectively as the GAP&GHP program (USDA AMS, 2006). Subsequently, as a result of the prevalence of foodborne illnesses linked to sprouts, FDA published *Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds* (hereinafter referred to as "FDA's 1999 Sprout Guidance") (FDA, 1999a), and *Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production* (FDA, 1999b). FDA has further published commodity-specific food safety guidelines for the melon supply chain, leafy greens, and fresh tomatoes (discussed in Chapter 2). Additional discussion on FDA guidance to industry is provided in Chapter 2.1.

- USDA has long been a partner with farmers to provide leadership on food, agriculture, natural resources, rural development, nutrition, and related issues based on sound public policy, the best available science, and efficient management (USDA, 2014). USDA continues to help farmers overcome challenges such as drought and climate change, food safety (though GAP&GHP Program Audits), grants and loans, and education, to name a few. Through AMS, USDA helps farmers by creating marketing opportunities to ensure the availability of food and agricultural products for consumers in domestic and export markets. Through NRCS, USDA provides farmers with financial and technical assistance to voluntarily apply conservation measures.
- Forty-five states require that certain farmers develop and adhere to Nutrient Management Plans as discussed in Chapter 3.4 that help to manage nutrient runoff to water resources.
- Universities, such as land grant universities, that receive special designation and federal support to conduct research on current challenges help the Government and the agricultural community find innovative solutions to overcome those challenges.
- State and industry marketing agreements have formed, in part, to collaboratively sell products while verifying compliance (among its membership) with food safety measures.

2.0 Description of the Proposed Action and Alternatives

FDA acknowledges that there may be direct, indirect, and cumulative effects on the human environment, of varying significance, if a final rule is enacted. These consequences may affect growers of produce that would be covered by the PS PR in various ways: some adverse, some beneficial. These effects are addressed in Chapter 4 and take into account the baseline agricultural conditions and background environmental conditions farmers face presently and how these effects may be altered through agency and industry partnerships. Also addressed is added flexibility within the agricultural water provision (subpart E) that FDA proposed in the supplemental proposed rule.

2.1 Proposed Action and Alternatives

In the PS PR, FDA proposed several science-based minimum standards for the safe production and harvesting of produce. This chapter discusses in detail potentially significant provisions (the determination of which was based on public and agency comments prior to and during the EIS scoping period, as discussed in Chapter 1.2) that are included within the scope of the EIS. This chapter also discusses those provisions which FDA determined would not result in significant environmental impact. For each potentially significant provisions, FDA identifies a range of possible alternatives, including a no action alternative. FDA also addresses those alternatives that were considered but eliminated from detailed environmental analysis. Finally, FDA, in coordination with USDA, identified the reasonably foreseeable actions, or management decisions, that businesses potentially affected by any final rule might take in order to come into compliance with, or to potentially avoid being subject to, the alternatives under consideration for inclusion in the final rule. Management decisions were considered reasonably foreseeable if they were in compliance with existing laws and regulations, if they would allow for compliance with the alternatives being considered, or if the technology is currently available or is in development and has been considered for the stated purpose. Management decisions that would only be suitable options for some covered produce were included, even if not a viable option for all covered produce. In response to the PS PR, FDA received some comments from industry detailing the steps that would be needed to be in compliance with the rule. Management decisions that were expressly stated or implied in these comments were considered in this EIS. We expected that farms would use one or a combination of the management decisions we identify in the EIS depending upon their individual conditions.

For each potentially significant provision discussed below, some information on baseline agricultural practices is provided in order to add context for existing industry practices, agency guidance, or regulatory conditions that growers of covered farms may already rely on to incorporate some level of food safety into their business. In some cases industry guidance may be more stringent than what FDA is proposing in the PS PR. Therefore, for farms that presently comply with such programs and practices, some of the potential impacts that are anticipated if a rule is finalized may be limited based on existing programs and practices.

Examples of Federal, State and industry guidance

As discussed in Chapter 1.9, USDA's GAP&GHP audit program offers voluntary independent audits of produce that are focused on best agricultural practices to verify that fruits and vegetables are produced, packed, handled, and stored in the safest manner possible to minimize risks of microbial contamination. The audits confirm adherence to FDA's recommendations made in its 1998 Guide, as well as other industry-recognized food safety practices (USDA AMS, 2013b).

It is important to note that while the GAP&GHP audit program remains popular, some farms use private audit companies. Audits conducted by USDA AMS as well as private third-party auditors check to see if the farm is following FDA's 1998 Guide and documenting its activities; however, third-party auditors tend to have varying criteria for their audits (GAPcertification.com, 2014).

The USDA AMS and other third-party auditors are in the process of switching over to the "Produce GAPs Harmonized Food Safety Standard," an industry-wide initiative effort that began in June 2009 to standardize the various audits so that farmers receive simply one audit by any credible third party that is acceptable to all buyers, thereby reducing confusion and the need for farmers to undergo multiple audits (United Fresh Produce Association, 2014). In 2011, USDA AMS incorporated the Produce GAPs Harmonized Food Safety Standard into its GAP audit program, and it is currently USDA AMS's preferred audit (USDA AMS, 2013c).

In June 2009, while the Produce GAPs Harmonized Food Safety Standard initiative was underway, USDA AMS received a petition for rulemaking and request for public hearing to establish a national marketing agreement for leafy green vegetables. This process resulted in the "Proposed National Marketing Agreement Regulating Leafy Green Vegetables," published in the *Federal Register* on April 29, 2011 (76 Fed. Reg. 24292).[28]

Prior to this petition for a national marketing agreement, members of the California leafy green vegetable industry had already initiated their own state marketing agreement. A similar program was implemented in Arizona in 2007. Both the California and Arizona marketing agreements were established in response to the September 2006 multi-state *E. coli* outbreak linked to fresh spinach, which resulted in the largest recall to date of fresh leafy green vegetables (see 76 Fed. Reg. 24292). While entering into such state/industry-specific marketing agreements are voluntary, the requirements of these agreements are mandatory for all signatories to such agreement in the respective state (76 Fed. Reg. 24292).

Table 2.1-1 provides examples of such marketing agreements and guidance to industry related to proposed potentially significant provisions. While many of these examples are state/industry-specific marketing agreements, USDA AMS provides oversight services for the commodity-specific audits required under these marketing agreements (USDA AMS, 2013d). Similar to

[28] It should be noted that the proposed "National Marketing Agreement Regulating Leafy Green Vegetables" proceedings were terminated on December 5, 2013, due to USDA AMS's decision that FDA's ongoing rulemaking, including the PS PR, may affect fundamental aspects of the proposed National Leafy Green Vegetable Marketing Agreement Program (78 Fed. Reg. 73111, December 5, 2013).

marketing agreements, farmers can also voluntarily become members of state/industry-specific GAP programs in which all members agree to comply with their programs' documented standards.

In addition to the marketing agreements and programs listed in Table 2.1-1, the table also lists an example of a required (non-voluntary) state-specific food safety program (Florida tomato industry's Tomato Good Agricultural Practices (T-GAP) program), as well as FDA's draft commodity specific guidance documents for melons, tomatoes, and leafy greens, which have not yet been issued in final form (78 Fed. Reg. 3504 at 3510).

Table 2.1-1. Examples of Federal, State, and industry specific guidance, programs, and marketing agreements related to FDA potentially significant provisions

Marketing agreements and Industry Guidance	Water Standards	Manure Standards	Domesticated and Wild Animal Grazing/Intrusion Standards
California Leafy Greens Marketing Agreement (CA LGMA)[a] And Arizona Leafy Greens Marketing Agreement (AZ LGMA)[b]	Pre-harvest Water (edible portions of crop are contacted by water, *e.g.*, overhead irrigation, pesticide/fungicide applications): analyze for generic *E. coli*; acceptable level is no more than 126 Most Probable Number (MPN)/100 milliliter (ml) (geometric mean (GM) of five samples) AND no more than 235 MPN/100 ml (all single samples) Pre-harvest Water (edible portions of crop are NOT contacted by water, *e.g.* furrow or drip irrigation, dust abatement water): analyze for generic *E. coli*; acceptable level is no more than 126 most probable number (MPN)/100 ml (GM of five samples) AND no more than 576 MPN/100 ml (all single samples) Postharvest Water (direct product contact, *e.g.* re-hydration, core in field, etc.): analyze for generic *E. coli*; acceptable level is negative or below detection limit	Raw: do not use in edible crop production; for previously treated fields, a 1-year waiting period shall be observed before planting any variety of leafy green crops Treated (Composted): if microbe levels are below corresponding action level numbers, then an application time interval of at least 45 days before harvest must be observed Treated (Heated): for non-validated process, observe application time interval of at least 45 days before harvest; for validated process, no application time interval is required	Allows growers to assess the animal risk they feel most threatens to contaminate their crops and determine the best ways to mitigate that risk; allows growers to assess the risk to subsequent crop production or production acreage that has experienced recent postharvest grazing by domesticated animals and take appropriate corrective action (as outlined in the marketing agreement)

Marketing agreements and Industry Guidance	Water Standards	Manure Standards	Domesticated and Wild Animal Grazing/Intrusion Standards
	(DL)/100 ml OR >1 ppm free Chlorine (pH 6.5 - 7.5) or > 650 milliVolts Oxidation Reduction Potential (ORP) (pH 6.5 - 7.5) after contact		
Mushroom Good Agricultural Practices Program (MGAP)[c]	Water used for irrigation should meet EPA microbial standards for drinking water	Receive and store materials in a manner that avoids the potential for cross-contamination between mushrooms and an unpasteurized substrate	Exclusion of pests (including insects, rodents, and birds) in fully enclosed mushroom growing buildings
Florida tomato industry T-GAPs program (mandatory participation for Florida tomato growers),[d] and Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain, Edition 2.0 (national, voluntary guidelines)[e]	Irrigation water must meet EPA's standard for *E. coli* in recreational waters (foliar application at the time of harvest must meet microbial standards for potable water); water used for washing tomatoes after harvest must meet microbial standards for potable water in 40 CFR Part 141.63	Only properly composted manure is allowed for use in tomato fields and greenhouses	Domestic animals and livestock must be excluded from tomato fields during growing and harvesting seasons; wild animals cannot be excluded but shall be minimized to the degree possible by methods identified by wildlife experts
Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons[f]	Ensure water is of sufficient microbial quality for intended purpose; monitor water disinfectant levels to ensure disinfectant is at sufficient levels to reduce potential risk of contamination	Evaluate soil amendments when melons directly contact soil	Monitor and reduce (to the extent possible) domestic animal, wildlife, and insect activity in melon production areas
Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens[g]	Ensure water is of appropriate microbial quality for intended use; test water source regularly	Recommendation to refrain from use of raw manure with any leafy greens crop; maximize the time interval between soil amendment application and time to harvest	Evaluate the risk to crop production on production acreage that has experienced recent postharvest grazing of domesticated animals; monitor and minimize domestic animal and wildlife activity in fields and production areas
Draft Guidance for Industry: Guide to Minimize Microbial	Utilize appropriate water treatment methods and identify alternative water	Recommendation to refrain from use of raw manure on tomato crop; maximize the	Recommend that domestic animals and livestock be excluded from tomato fields

Marketing agreements and Industry Guidance	Water Standards	Manure Standards	Domesticated and Wild Animal Grazing/Intrusion Standards
Food Safety Hazards of Tomatoes[h]	sources, if necessary, to ensure water quality is sufficient for intended use; establish and follow corrective actions if water testing indicates a potential problem	time interval between soil amendment application and time to harvest	and measures be taken to minimize wildlife presence using methods identified by wildlife experts

[a] Source: CA LGMA, 2013
[b] Source: AZ LGMA, 2013
[c] Source: Penn State University (Penn State) and the American Mushroom Institute (AMI), 2010
[d] Source: Florida Department of Agriculture and Consumer Services (DACS), 2012
[e] Source: North American Tomato Trade Work Group (NATTWG) and United Fresh Produce Association (United Fresh), 2008
[f] Source: FDA, 2009a
[g] Source: FDA, 2009b
[h] Source: FDA, 2009c

Proposed actions and alternatives

This section specifically addresses the potentially significant provisions which FDA determined may significantly affect the quality of the human environment. For each provision (*i.e.*, subparts E, F, I, and A), FDA provides a brief discussion or definition of the provision; provides information on baseline agricultural conditions that adds context for the existing industry practices, agency guidance, or regulatory conditions that growers of covered farms may operate within; identifies the alternative that would help FDA best "fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors" (CEQ, 1981); discusses alternatives to the proposed provision; and identifies management decisions that may be applicable to those alternatives.

(Subpart E) Standards directed to agricultural water (proposed §§ 112.41 to 112.50)

Agricultural water for the purposes of this document, as defined in proposed § 112.3(c), is water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food-contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).

Baseline agricultural conditions

There are no federal regulations presently in place to regulate agricultural water quality with respect to minimizing food safety hazards. There are, however, some regional or state water suppliers (*e.g.*, irrigation districts, acequia associations) or growers association standards for agricultural water (including surface contact irrigation with covered crops, indirect irrigation [*e.g.*, drip/furrow], or processing, holding, or cooling waters). Participation in these programs tends to be voluntary, with some exceptions, but such programs provide benefits by increasing growers' selling potential and market exposure, which makes participation attractive for many growers.[29] Appendix B offers discussion on irrigation systems specifically.

In our Draft QAR (2013c), FDA concluded that the following practices or pathways for pathogenic transport, relative to agricultural water, are important causes of contamination of produce:

- Agricultural water can be a source of contamination of produce.
- Public Drinking Water Systems (domestically regulated by EPA) have the lowest relative likelihood of contamination due to existing standards and routine analytical testing.
- Groundwater has the potential to pose a public health risk, despite the regulation of many U.S. public wells.
- There is a significant likelihood that U.S. surface waters will contain human pathogens, and surface waters pose the highest potential for contamination and the greatest variability in quality of the agricultural water sources.
- Susceptibility to runoff significantly increases the variability of surface water quality.
- Water that is applied directly to the harvestable portion of the plant is more likely to contaminate produce than water applied by indirect methods that are not intended to, or not likely to, contact produce.
- Proximity of the harvestable portion of produce to water is a factor in the likelihood of contamination during indirect application.
- Timing of water application in produce production before consumption is an important factor in determining likelihood of contamination.
- Commodity type (growth characteristics, *e.g.*, near to ground) and surface properties (*e.g.*, porosity) affect the probability and degree of contamination.
- Microbial quality of source waters, method of application, and timing of application are key determinants in assessing relative likelihood of contamination attributable to agricultural water use practices.

[29] An example of a mandatory state program is the T-GAPs, which is mandatory for tomato growers in Florida and relate to field and greenhouse production. See Table 2.1-1.

Proposed action and alternatives related to agricultural water

In the *Federal Register* notice announcing a public meeting on scoping of the EIS (79 Fed. Reg. 13593, March 11, 2014; hereinafter referred to as "the Public Scoping *Federal Register* notice") and the corresponding public meeting held on April 4, 2014, FDA discussed potential alternatives to provisions proposed in FDA's 2013 proposed rule. For the purposes of those discussions, FDA listed the following proposed provision and potential alternatives related to the microbial quality standard for agricultural water that is used in a direct application method during growing or produce (other than sprouts):

Provision proposed by FDA per the 2013 proposed rule

Proposed § 112.44(c) (in relevant part), in the 2013 proposed rule, reads as follows:

> When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method you must test the quality of water in accordance with one of the appropriate analytical methods in subpart N. If you find that there is more than 235 colony forming units (CFU) [or most probable number (MPN), as appropriate] generic *E. coli* per 100 ml for any single sample or a rolling geometric mean (GM, n=5) of no more than 126 CFU (or MPN, as appropriate) per 100 ml of water, you must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in this paragraph.

Proposed § 112.45 would require that growers test their agricultural water at the beginning of each growing season, and every three months thereafter during the growing season, except that there is no requirement to test water when (1) the grower receives water from a public water system as defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State approved to administer the SDWA public water supply program, and the grower has Public Water System results or certificates of compliance that demonstrate that the water meets that requirement; (2) the grower receives water from a public water supply that furnishes water that meets the microbial requirement described in § 112.44(a), and has public water system results or certificates of compliance that demonstrate that the water meets that requirement; or (3) the grower treats water in accordance with the requirements of proposed § 112.43.

For untreated surface water sources where a significant quantity of runoff is likely to drain into the source (*e.g.*, a river or natural lake), the grower would be required to test the untreated water every 7 days during the growing season. Where untreated surface water comes from any source where underground aquifer water is transferred to a surface water containment constructed and maintained in a manner that minimizes runoff drainage into the containment (*e.g.*, an on-farm man-made water reservoir), then the grower would be required to test the untreated surface water at least once each month during the growing season.

Proposed § 112.3(c) would define "direct water application method" as using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food-contact surfaces during use of the water.

Potential Alternatives (identified in the Public Scoping Federal Register notice)

1. No action;

2. As proposed, *i.e.*, no more than 235 CFU (or MPN, as appropriate) generic *E. coli* per 100 ml for any single sample or a rolling GM (n=5) of no more than 126 CFU (or MPN, as appropriate) per 100 ml of water;

3. No detectable generic *E. coli* per 100 ml;

4. A flexible water quality standard that allows for adjustment to a specified microbial quality standard based on mitigation steps that occur after application of agricultural water and prior to consumption. For example, WHO recommends a minimum microbial quality for water of 1,000 CFU generic *E. coli* per 100 ml for water used on root crops that are eaten raw, and 10,000 CFU generic *E. coli* per 100 ml for water used on leaf crops, which is dependent upon a 2-log[30] reduction due to die-off between last irrigation and consumption (includes die-off in the field and during distribution) and a 1-log reduction attributed to washing prior to consumption (WHO, 2006); and,

5. For each of the options above, consider the environmental impacts of two different interpretations of the definition of "direct water application method" in § 112.3(c): (1) to include root crops that are drip irrigated and (2) to exclude root crops that are drip irrigated.

Supplemental proposed rule

In the supplemental proposed rule, FDA amended proposed § 112.44(c) to update the microbial quality standard for water that is used during growing of produce (other than sprouts) using a direct application method in a way that is consistent with EPA's current recreational water standard (*i.e.*, a GM of samples not to exceed 126 CFU of generic *E. coli* per 100 ml of water and (when applicable) a statistical threshold value of samples not to exceed 410 CFU of generic *E. coli* per 100 ml of water) (79 Fed. Reg. 58434 at 58471). In addition, FDA proposed two new provisions within proposed § 112.44(c) (*i.e.*, § 112.44(c)(1) and (c)(2)) to incorporate additional flexibility and provided means to achieve the amended proposed microbial water quality standard (described under Alternative I, below).

[30] The term "log" refers to logarithm, which has many applications in mathematics, but in this definition refers to exponentially reducing the measured amount per 100 milliliters (ml) that a pathogen persists in any particular media (water, soil, surface of produce, etc.).

In the supplemental proposed rule, FDA retained its previous proposed provision that would establish that the use of public water supplies operating in accordance with the SDWA would not require the grower to sample and test the water if the grower has a certificate of compliance that demonstrates that the water meets the SDWA requirement (proposed § 112.45(a)).

In addition, FDA amended its proposed requirements for testing untreated surface water subject to proposed § 112.44(c). Under proposed § 112.45(b), growers that use untreated surface water would be required to conduct a baseline survey to develop an agricultural water quality profile, using both a GM and statistical threshold value (STV) to characterize the microbial quality of each source of untreated surface water. Conducting a baseline survey to develop a water quality profile would entail collecting and testing a minimum of 20 samples over a minimum period of 2 years, consisting of samples of agricultural water as it is used during growing activities using a direct water application method, collected during a time period as close as practical to harvest. The grower would be required to conduct an annual survey to verify the water quality profile. In accordance with proposed § 112.45(b)(3), if the grower knows or has reason to believe that the water quality profile (either the initial or the updated/annually revised profile) no longer represents the quality of the water, the grower would be required to develop a new water quality profile and modify water use as soon as practical and no later than the following year. A farm would be required to develop a new water quality profile at least once every ten years.

FDA also amended its proposed requirements for testing ground water subject to proposed § 112.44. Under proposed § 112.45(c)), a grower that uses untreated ground water would be required to test the quality of each source of the ground water at least four times during the growing season over a 1-year period using a minimum of four samples collected during a time period as close as practical to harvest. If the samples tested meet the requirements of proposed § 112.44 (*i.e.*, no detectable generic E. coli per 100 mL under 112.44(a) or a geometric mean of generic E. coli of 126 CFU or less per 100 mL under 112.44(c), as applicable), the grower would be required test once annually thereafter, using a minimum of one sample collected during a time period as close as practical to harvest. The grower would be required to resume testing at least four times per growing season or year if any annual test fails to meet the applicable microbial standard in § 112.44.

Other Considerations

FDA received several comments to the supplemental proposed rule regarding the provisions of subpart E, including on proposed §§ 112.44(c), 112.44(d), 112.45(b), and 112.45(c). Some of these comments included questions and recommendations, among other topics, on the number of samples that would be required to be collected in order for a farm to establish or update its water quality profile; the time-frame within which samples for the water quality profile would need to be collected; any maximum time

interval related to the microbial die-off rate that may be applied to achieve the proposed microbial quality criteria; and the use of alternative water quality criteria and water testing frequencies.

FDA is presently considering these and other comments, which may result in amendments in the relevant provisions of any final rule that may result. While there may be some adjustments associated with the costs for farmers to comply with any amended final requirements, FDA does not believe that any associated cost adjustments would result in additional environmental impacts not already considered. The commenters primarily requested that FDA consider requiring fewer samples or longer time-frames for testing or that FDA establish a maximum time interval related to the microbial die-off rate. We expect impacts related to any such requirements to fall within the spectrum of the alternatives analyzed, even if the impacts may not be identical to what was considered. We also expect any such changes would result in minimal cost adjustments, and we see no indication that such adjustments would change the level of significance assessed in this Final EIS (*e.g.*, from not significant to significant). If amendments are made to these provisions, FDA will explain its rationale for any such amendments in the Final Rule. Any cost-related impacts would be described in detail in an accompanying FRIA, and any related environmental impacts would be summarized in the ROD.

Potential alternatives (analyzed in this EIS)[31]

This Final EIS analyzes the following provision in the supplemental proposed rule (proposed § 112.44(c)), including root crops that are irrigated with low flow measures, (Alternative IV-a, see the expanded discussion under Alternative IV in the text that follows) as the alternative that would best "fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors" (CEQ, 1981) related to the microbial quality standard for agricultural water when agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method:

1. As proposed, *i.e.*, an STV not exceeding 410 CFU of generic *E. coli* per 100 ml of water and a GM not exceeding 126 CFU of generic *E. coli* per 100 ml of water, along with options to achieve the standard by applying either a time interval between last irrigation and harvest using a microbial die-off rate of 0.5 log per day and/or a time

[31] This proposed standard incorporates the concept of "a flexible water quality standard" from previous Alternative 4, which was discussed under the subheader, *Potential Alternatives (identified in the Public Scoping Federal Register notice)*, and also identified in the Public Scoping *Federal Register* notice and in documents discussed at the public meeting, *i.e.*, a flexible water quality standard that allows for adjustment to the specified microbial quality standard based on steps that occur after application of agricultural water and prior to consumption.

interval between harvest and end of storage using an appropriate microbial die-off or removal rates, including during activities such as commercial washing.[32]

This Final EIS analyzes the following three additional alternatives related to the microbial quality standard for agricultural water:

2. A microbial quality standard of no more than 235 CFU (or MPN, as appropriate) generic *E. coli* per 100 ml for any single sample or a rolling GM (n=5) of no more than 126 CFU (or MPN, as appropriate) per 100 ml of water, as originally proposed in the 2013 proposed rule;

3. As proposed (*i.e.*, Alternative I), but with an additional criterion establishing a maximum generic *E. coli* threshold;[33] and,

4. For each of the options above, consider the environmental impacts using an interpretation of the definition of "direct water application method" in § 112.3(c) to include root crops that are irrigated using low-flow methods, *e.g.*, drip irrigation, where contact is intended to, or likely to, occur with the harvestable or harvested portion of the crop below the soil. The analysis of Alternative I through III assumes that agricultural water applied using direct water application methods would not be in direct contact with covered crops unless the harvestable or harvested portion of the crop was above the soil surface to some extent, *e.g.*, carrots, where a portion of the vegetable and the edible greens would be above the surface.

Alternative I. As proposed (proposed § 112.44(c), as amended)

When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method, the grower must test the quality of water in accordance with one of the appropriate analytical methods in subpart N (§§ 112.151 – 112.152) to develop and verify the water quality profile of the water source as described in § 112.45(b)(1). Using the water quality profile as described in § 112.45(b)(1), if (when applicable) the estimate of the STV

[32] This proposed standard incorporates the concept of "a flexible water quality standard" from previous Alternative 4, which was discussed under the subheader, *Potential Alternatives (identified in the Public Scoping Federal Register notice), and also* identified in the Public Scoping *Federal Register* notice and in documents discussed at the public meeting, *i.e.*, a flexible water quality standard that allows for adjustment to the specified microbial quality standard based on steps that occur after application of agricultural water and prior to consumption.

[33] In the supplemental proposed rule (79 Fed. Reg. 58434 at 58444), FDA acknowledged that, under FDA's proposed approach, there would be no maximum threshold for a baseline of generic *E. coli* above which the agricultural water would be precluded from use in direct application during growing such that a covered farm would not be able to apply an appropriate time interval between last irrigation and harvest or between harvest and end of storage. FDA asked for public comment on whether FDA should establish a maximum level of *E. coli* (GM and/or STV) above which the water should not be permitted for use in direct application (until specific follow-up actions are taken to ensure it meets the recommended microbial quality requirements) and, if so, what an appropriate maximum level would be. Given FDA's request for public comment on this issue, we are including this new potential Alternative 3.

of samples exceeds 410 CFU of generic *E. coli* per 100 ml of water, or if the GM of samples exceeds 126 CFU of generic *E. coli* per 100 ml of water, the grower must either:

(1) Apply a time interval (in days) between last irrigation and harvest using a microbial die-off rate of 0.5 log per day (or an alternative microbial die-off rate consistent with paragraph (d)(2) of this section) to achieve a (calculated) log reduction of the GM of generic *E. coli* level to 126 CFU or less per 100 ml and (when applicable) of the STV to 410 CFU or less per 100 ml, or an alternative microbial standard consistent with paragraph (d)(1); or

(2) Apply a time interval (in days) between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage and/or appropriate microbial removal rates during activities such as commercial washing to achieve a (calculated) log reduction of the GM of generic *E. coli* level to 126 CFU or less per 100 ml and (when applicable) of the STV to 410 CFU or less per 100 ml (or an alternative microbial standard consistent with paragraph (d)(1) of this section), provided there is adequate supporting scientific data and information. The grower may apply this time interval in addition to the time interval in accordance with paragraph (c)(1) of this section; or

(3) Immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in this paragraph. Before the grower may use the water source and/or distribution system again for the uses described in this paragraph, they must either reinspect the entire agricultural water system under their control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and retest the water to determine if those changes were effective; or treat the water in accordance with the requirements of § 112.43.

In the 2014 supplemental proposed rule, FDA also amended proposed § 112.45, resulting in a tiered approach to testing untreated surface water and untreated groundwater. The proposed approach would allow farms to make decisions about safe use of available water sources prior to the beginning of the next growing season, adjust testing frequencies dependent on long-term test results, and ultimately reduce the required frequency of testing. Proposed § 112.45 would also establish specific sampling frequencies for untreated surface water and untreated groundwater sources.

Alternative II. Originally proposed. 235 CFU per 100 ml (more restrictive)

The conditions set forth under Alternative I, including conditions for log die-off of pathogens and for the tiered approach to water testing requirements, would not apply to this alternative.

When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method, the grower must test the quality of water in accordance with one of the appropriate analytical methods in subpart N (§§ 112.151 – 112.152). If there is more than 235 CFU (or MPN, as appropriate) generic *E. coli* per 100 ml for any single sample or a GM (n=5) of no more than 126 CFU (or MPN, as appropriate) per 100 ml of water, the grower

must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described [in § 112.44(c)].

Alternative III. As proposed, but establishing a maximum generic E. coli threshold (more restrictive)

As proposed (*i.e.*, Alternative I), but with an additional criterion establishing a maximum generic *E. coli* threshold. In the supplemental proposed rule, FDA requested public comment on any potential maximum threshold.

Alternative IV. Direct water application method

As proposed, FDA defines "direct water application method" (§ 112.3(c)) as using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food-contact surfaces during use of the water.

For Alternatives I, II, and III, FDA considered the environmental impacts of an interpretation of the definition of "direct water application method" that assumes that agricultural water applied using direct water application methods would not be in direct contact with covered crops unless the harvestable or harvested portion of the crop was above the soil surface to some extent, *e.g.*, carrots, where a portion of the vegetable and the edible greens would be above the surface. Conversely, Alternative IV considers an interpretation of the definition of "direct water application method" that would include root crops that are irrigated using low-flow methods, such as drip irrigation where contact is intended to, or likely to, occur with the harvestable or harvested portion of the crop below the soil. This essentially creates 3 subalternatives:

Alternative IV-a: An STV not exceeding 410 CFU of generic *E. coli* per 100 ml of water and a GM not exceeding 126 CFU of generic *E. coli* per 100 ml of water, along with options to achieve the standard by applying either a time interval between last irrigation and harvest using a microbial die-off rate of 0.5 log per day and/or a time interval between harvest and end of storage using an appropriate microbial die-off or removal rates, including during activities such as commercial washing. Alternative IV-a applies Alternative I to all covered produce including root crops that use low-low irrigation methods, *e.g.,* drip irrigation.

Alternative IV-b: When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method the grower must test the quality of water in accordance with one of the appropriate analytical methods in subpart N (§§ 112.151 – 112.152). If there is more than 235 CFU (or MPN, as appropriate) generic *E. coli* per 100 ml for any single sample or a GM (n=5) of no more than 126 CFU (or MPN, as appropriate) per 100 ml of water, the grower must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described [in § 112.44(c)].Alternative IV-b applies Alternative II to all covered produce including root crops that use low-flow irrigation methods, *e.g.*, drip irrigation.

Alternative IV-c: This alternative incorporates the provision, as proposed under Alternative I and, therefore, Alternative IV-a, but with an additional criterion establishing a maximum generic *E. coli* threshold. In the supplemental proposed rule, FDA requested public comment on any potential maximum threshold. Alternative IV-c applies Alternative III to all covered produce including root crops that use low-flow irrigation methods, *e.g.*, drip irrigation.

In the 2013 proposed rule, FDA proposed to define "direct water application method" as using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food-contact surfaces during use of the water (proposed § 112.3). FDA received public comments on this proposed definition requesting clarification on whether low-flow irrigation methods, *e.g.*, drip irrigation, on root crops, such as onions and carrots, would be considered a direct water application method, as proposed. FDA is currently considering comments received on this issue for the final rule. Therefore, under Alternative IV, the Final EIS considers the environmental impacts of including root crops that use low-flow irrigation methods (*e.g.*, drip irrigation) in the context of any final definition of "direct water application method" and in the context of Alternatives I through III.

As discussed at the beginning of this section, FDA proposed to define agricultural water (see above) as water that is intended to, or is likely to, contact covered produce or food-contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods (*e.g.*, overhead), water used for preparing crop sprays and water used for growing sprouts) and in harvesting, packing and holding activities. Under the proposed definition, generally, water used for drip or furrow irrigation in apple orchards would not be considered agricultural water because the water is unlikely to contact the harvestable portion of the crop. Water that does not have the potential to come in contact with produce covered by this rule would not be agricultural water and therefore would not be subject to the standards directed to agricultural water.

Appendix B discusses in more detail various types of irrigation methods, including direct irrigation methods commonly used throughout the United States.

Management decisions

Table 2.1-2 lists a set of management decisions that a grower could reasonably be expected to make if the PS PR were finalized using one of the four alternatives presented. For each alternative FDA and USDA determined that there are some basic, common, management decisions that a grower may consider in order to meet the requirements of subpart E: use chemical treatment, change irrigation mechanism, change water source, or stop growing covered produce. Such decisions would be based upon a variety of factors (*e.g.*, crop type, soil conditions, environmental conditions, costs). Given the added flexibility FDA proposed in the 2014 supplemental proposed rule (Alternative I), it is reasonably foreseeable that a grower may decide that none of the aforementioned management decisions are applicable to their decision-making process, and therefore, that a mechanism to account for pathogenic die-off is a more reasonable option.

Table 2.1-2. Management decisions, by alternative proposed under subpart E

Alternative I. As Proposed. GM ≤ 126 CFU generic *E. coli*/100 ml and STV ≤ 410 CFU/100 ml	**Alternative II.** 235 CFU (or MPN) generic *E. coli* /100 ml single sample or a GM of no more than 126 CFU (or MPN)/100 ml	**Alternative III.** As proposed (*i.e.*, Alternative 1), with an additional criterion establishing a maximum generic *E. coli* threshold	Alternative IV-a to IV-c. Alternatives for direct water application method
Use chemical treatment	Use chemical treatment	Use chemical treatment	Use chemical treatment
Change irrigation mechanism	Change irrigation mechanism	Change irrigation mechanism	Change irrigation mechanism
Change water source	Change water source	Change water source	Change water source
Stop growing covered produce	Stop growing covered produce	Stop growing covered produce	Stop growing covered produce
Add mechanism to account for die-off			Add mechanism to account for die-off, if applicable

(Subpart F) Standards directed to biological soil amendments of animal origin and human waste (proposed §§ 112.51 to 112.60)

FDA defines biological soil amendments (BSAs) as any soil amendment containing biological materials such as humus, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination. BSAs of animal origin consist, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts, or table waste, alone or in combination. The term ‘‘biological soil amendment of animal origin’’ does not include any form of human waste (proposed § 112.3).

Chapter 3.5 Waste Generation, Disposal, and Resource Use discusses raw (untreated) and treated manure (compost), where these BSAs are produced in relation to covered produce operations, the prevalence of use of BSAs in agriculture, and the benefits and problems of applying these BSAs. Additional information on BSAs is provided in Appendix C.

FDA considered comments that it received on the 2013 proposed rule and during the EIS scoping period with respect to the 9 month minimum application interval for use of raw manure originally proposed in § 112.56(a)(1)(i). As a result, in the supplemental proposed rule, FDA deferred a decision on an appropriate minimum application interval for use of raw manure until FDA pursues certain actions, including a robust research agenda, risk assessment, and efforts to support compost infrastructure development, in concert with USDA and other stakeholders. With respect to this Final EIS, FDA considered additional comments received during the Draft EIS public comment period but made no substantial changes to the alternatives or the impact assessment in Chapter 4, other than to revise our analysis of combined environmental impacts to soils in Chapter 4.7, to provide more detail and clarity on the reasoning behind the severity of certain impacts (see Appendix E and Chapter 4.3 and 4.4). As such, FDA determined it is still appropriate to evaluate the potential environmental impacts from implementing proposed § 112.56(a)(1)(i) (as well as

alternatives identified in this chapter), as we still intend to finalize a provision at a future point in time. Such analysis has value in order to establish or improve upon the methodology for identifying environmental consequences, costs, and risks associated with implementing the proposed action or one of its alternatives in the future, at a time when FDA has completed its research, risk assessment, and public outreach. Including the analysis further allows FDA to evaluate the cumulative potential impacts of the final action. At that time, it may be necessary to either update the Record of Decision (ROD) or prepare a NEPA re-evaluation or supplemental statement in accordance with 40 CFR § 1502.9(c), based on FDA's findings.

In addition, as described in the supplemental proposed rule, proposed § 112.56(a)(4)(i) would establish that if the BSA of animal origin is treated by a composting process and is applied in a manner that minimizes the potential for contact with covered produce during and after application, then the minimum application interval (*i.e.*, time between application and harvest) is 0 days.

Baseline agricultural conditions

In its Draft QAR (2013c), FDA concluded that the following agricultural practices or pathways for pathogenic transport, relative to soil amendment use, are important causes of contamination of produce:

- Soil amendments can be a source of contamination of produce.
- BSAs of animal origin have a greater likelihood of containing human pathogens than do chemical or physical soil amendments or those BSAs that do not contain animal waste (*e.g.*, plant-based soil amendments).
- Animal waste subject to treatment, such as chemical and physical treatments and composting, has relatively lower levels of human pathogens than untreated animal waste.
- Composting is less likely than controlled chemical or physical treatments to fully eliminate human pathogens from animal waste.
- Incompletely treated, or re-contaminated, BSAs of animal origin may also contain human pathogens.
- Human pathogens in untreated or composted BSAs of animal origin, once introduced to the growing environment, will eventually die off, but the rate of die-off is dependent upon a number of environmental, regional, and other agro-ecological factors.
- Treatments, such as chemical and physical treatments and composting, can effectively reduce the levels of human pathogens in animal waste.
- Among application methods, application of soil amendments in a manner in which they contact the harvestable portion of the crop presents the greatest likelihood of contamination, especially when applied close to harvest.

Based on FDA 2014 estimates in the supplemental PRIA, 35,503 farms, or 1.70 percent of 2,109,303 total U.S. farms, would be covered by the PS PR, which represents an estimated 18.7

percent of all produce-growing farms (FDA, 2014b). According to 2013 estimates,[34] 4,438 covered farms used BSAs (Table 2.1-3).[35] Not all BSAs are of animal origin; some organic farms use green manure.[36] Of the 4,438 covered farms using BSAs, approximately 821 farms used untreated BSAs (raw manure). The remainder of covered farms may use chemical fertilizers already on the market to augment soil quality with nutrients such as nitrogen (N), phosphorus (P), and potassium (K), which promote plant growth.

Table 2.1-3. Covered domestic farms using treated and untreated BSAs

	Very small	Small	Large	Total
Covered farms that use manure	2,748	562	1,128	**4,438**
[a] Livestock and produce farms	1,819	354	656	**2,829**
Estimated number of farms using untreated (raw) manure	337	66	121	524
Estimated number of farms using treated manure	1,483	289	534	2,306
[b] Organic produce farms using green manure or BSAs of animal origin	402	55	131	**588**
Estimated organic farms using untreated manure	74	10	24	109
Estimated other farms using BSAs of animal origin	527	153	342	**1,021**
Estimated farms using untreated manure	97	28	63	188

[a] Source: USDA NASS 2007 Survey (2012 survey data not available at the time of estimates) (USDA NASS, 2009d)
[b] Source: USDA NASS 2007 National Organic Survey (2012 survey data not available at the time of estimates) (USDA NASS, 2010)
Note: The bolded numbers in the "Total" column represents the reported total numbers for those categories (covered farms, livestock and produce farms, organic produce farms, and other farms).

According to 2013 estimates, there were 4,473,575 total produce acres (FDA, 2013b); of these acres, 81 percent are managed by large farms, 9 percent by small farms, and approximately 10 percent by very small farms. The 4,438 covered farms have an associated 549,437 produce acres and 573,016 manure acres.[37] Of produce acres, approximately 70,134, or 12.8 percent, used

[34] Because the 2013 estimates used a definition of $25,000 average annual monetary value of total "food" and the supplemental PRIA used average annual monetary value of "produce," there are now fewer covered farms. Overall 2013 and 2014 estimates are mostly comparable, but there would also be fewer covered farms now using BSAs.
[35] The data used to estimate farms using BSAs of animal origin, and also presented in Tables 2.1-3 and 2.1-4 are presented in FDA's PRIA (FDA, 2013b). These data were compiled using information that was extracted from the 2007 USDA NASS survey, with estimates made using certain assumptions as described in the 2013 PRIA, Section IV.G.3. Biological Soil Amendments.
[36] Green manure is a crop that is grown then plowed into the soil or otherwise left to decompose for the purpose of soil improvement (e.g., clover, rye or soybeans). Green manure would not be regulated by the final rule.
[37] In order to determine a conservative estimate for the amount of produce acres to which untreated manure is applied, FDA reviewed responses from farmers to USDA NASS Surveys. Where farms reported that they grew produce commodities, FDA calculated the amount of produce acres where the farms responded raw manure was applied. In

untreated BSAs of animal origin.[38] Table 2.1-4 shows the total produce acres, total produce and manured acres of covered farms that use BSAs, and breaks down these farms into three categories: livestock and produce farms, organic produce farms using green manure or BSAs of animal origin, and other farms using BSAs.

Table 2.1-4. Covered farms and associated produce acres (including manured acres)

	Very small	Small	Large	Total
Total produce acres	447,342	389,610	3,636,623	**4,473,575**
Percentage produce acres by size	10%	9%	81%	**100%**
Covered farms that use manure	2,748	562	1,128	**4,438**
Total number of produce acres	56,441	52,114	440,882	**549,437**
Total number of manure acres	112,987	67,622	392,407	**573,016**
[a] Livestock and produce farms	1,819	354	656	**2,829**
Estimated manured produce acres (treated and untreated totals)	29,036	23,882	118,556	171,474
Estimated number of untreated (raw) manure acres	4,065	3,344	16,598	24,006
Estimated number of treated (composted) manure acres	24,971	20,539	101,958	147,468
[b] Organic produce farms using green manure or BSAs of animal origin	402	55	131	**588**
Estimated number of manured produce acres	5,385	4,489	56,542	66,416
Estimated organic produce acres using untreated manure	754	629	7,916	9,298
Estimated other farms using BSAs of animal origin	527	153	342	**1,021**
Estimated number of remaining manured acres	22,020	23,742	217,310	263,072
Estimated number of remaining untreated manured acres	3,083	3,324	30,423	36,830

[a] Source: USDA NASS 2007 Survey (2012 survey data not available at the time of analysis) (USDA NASS, 2009d)
[b] Source: USDA NASS 2007 National Organic Survey (2012 survey data not available at the time of analysis) (USDA NASS, 2010)

Chapter 3.4.2 provides an overview of existing regulations that govern the use or application of BSAs of animal origin. Similar to agricultural water, there are some growers association standards that are currently in place. Many of these programs are voluntary. Table 2.1-1 provides some examples of such agreements and their associated guidelines for applying BSAs.

instances where farms reported more manured acres then all produce acres, FDA determined that those farms also grew non-covered commodities and that the farm also applied manure to those crops. If the amount of manured acres totaled more than the amount of produce acres, FDA estimated that manure was applied to all produce acres. There are no data to verify this estimate.

[38] 70,134 is the sum of the amount of estimated manured produce acres as shown in Table 2.1-4 for livestock and produce farms that applied untreated manure (24,006 produce acres), organic produce farms that applied untreated manure (9,298 produce acres), and for other farms that applied untreated manure (36,830 produce acres).

Untreated: Alternative I. Nine months (Originally proposed as § 112.56(a)(1)(i)- Decision Deferred)

As proposed in the 2013 proposed rule, if the BSA of animal origin is untreated and is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, then the minimum application interval (*i.e.*, time between application and harvest) must be nine months (originally proposed as § 112.56(a)(1)(i)).

As described in the 2013 proposed rule and in the conclusions of the Draft QAR, soil amendments can be a source of contamination to produce, and BSAs of animal origin have a greater likelihood of containing human pathogens than do chemical or physical soil amendments or those that do not contain animal waste. FDA also noted that human pathogens in untreated or composted BSAs, once introduced to the growing environment, will eventually die-off, but the rate of die-off is dependent upon a number of environmental, regional, and other agro-ecological factors (see 78 Fed. Reg. 3504 at 3523), which is subject to continued study.

Untreated: Alternative II. Zero days (less restrictive than Alternative I)

If the BSA of animal origin is untreated and is applied in a manner that does not contact covered produce during application and minimizes the potential for contact after application, then the minimum application interval *(i.e.*, time between application and harvest) must be zero days.

This alternative is considered to be closer to baseline conditions for growers that do not presently participate in USDA's organic program or that do not voluntarily participate in marketing agreements (examples listed in Table 2.1-1), and therefore may apply untreated BSAs of animal origin until FDA pursues certain actions. Therefore, an alternative that would best meet the statutory mission and responsibilities has not been identified. The environmental impacts of the deferred action are equivalent to those assessed in this alternative as growers would still be obligated to apply untreated BSAs in a manner that minimizes contact with covered produce during application.

For the purpose of the aggregate analysis, in the absence of a decision on the alternative which would fulfill the statutory mission, the impacts associated with the 0-day application interval were included as the environmental impacts associated with this alternative. Such impacts are indicative of current practice and any minor shifts in this practice that may be anticipated.

Untreated: Alternative III. Application interval consistent with Organic Regulations (less restrictive than Alternative 1)

The USDA organic regulations specify application intervals for the use of raw manure as a soil amendment *(i.e.*, 90 days and 120 days before harvest) depending on whether the edible portion of the crop contacts the soil (as specified in 7 CFR 205.203(c)(1)).

Untreated: Alternative IV. Application interval of 6 months (less restrictive than Alternative I)

If the BSA of animal origin is untreated and is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, then the minimum application interval (*i.e.*, time between application and harvest) must be six months.

Untreated: Alternative V. Application interval of 12 months (more restrictive than Alternative I)

If the BSA of animal origin is untreated and is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, then the minimum application interval (*i.e.*, time between application and harvest) must be 12 months.

Treated: Alternative I. Application interval of zero days (alternative that will best fulfill FDA's statutory mission and responsibilities, as proposed (proposed § 112.56(a)(4)(i))

As amended, proposed § 112.56(a)(4)(i)) would establish that if the BSA of animal origin is treated by a composting process in accordance with the requirements FDA proposed in § 112.54(c) to meet the microbial standard proposed in § 112.55(b), and is applied in a manner that minimizes the potential for contact with covered produce during and after application, then the minimum application interval (*i.e.*, time between application and harvest) is zero days.

Treated: Alternative II. Application interval of 45 days

If the BSA of animal origin is treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b), then the BSA of animal origin must be applied in a manner that minimizes the potential for contact with covered produce during and after application, and then the minimum application interval is 45 days.

Treated: Alternative III. Application interval of 90 days

If the BSA of animal origin is treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b), then the BSA of animal origin must be applied in a manner that minimizes the potential for contact with covered produce during and after application, and then the minimum application interval is 90 days.

Management decisions

Table 2.1-5 lists a set of management decisions that a grower may make if the PS PR were finalized. The potential environmental impacts of these decisions are addressed in Chapter 4. There are two distinct sets of management decisions that FDA and USDA identified for these alternatives. This is because the potential pathogen load is different in untreated BSAs of animal origin as compared to treated BSAs of animal origin (explained further in Chapter 3.4). Also, *how*

and *when* a grower applies untreated versus treated BSAs of animal origin may be different for a variety of factors (including, but not limited to availability, compliance with marketing agreements, industry best practices). Therefore, growers may decide to switch to treated BSAs of animal origin if they are presently using untreated material, which is why that management decision is represented only under alternatives considered for untreated BSAs of animal origin.

For all alternatives under treated and untreated BSAs of animal origin, FDA and USDA determined that the most reasonably foreseeable, common management decisions include switching to BSAs of non-animal origin (see Chapter 3.4) or chemical fertilizers, applying the requisite waiting period, or changing the application of BSAs of animal origin to a mode that the material will not contact covered produce during and after application.

Table 2.1-5. Management decisions, by alternative proposed under subpart F

Untreated BSAs					Treated BSAs		
Alternative I. Minimum application interval of 9 months	**Alternative II. Minimum application interval of 0 days**	**Alternative III. Minimum application interval of 90/120 days**	**Alternative IV. Minimum application interval of 6 months**	**Alternative IV. Minimum application interval of 12 months**	**Alternative I. Minimum application interval of 0 days**	**Alternative II. Minimum application interval of 45 days**	**Alternative III. Minimum application interval of 90 days**
Switch to treated material	Switch to treated material	Switch to treated material	Switch to treated material	Switch to treated material	Use BSAs of non-animal origin or processed	Use BSAs of non-animal origin or processed	Use BSAs of non-animal origin or processed
Use BSAs of non-animal origin	Use BSAs of non-animal origin	Use BSAs of non-animal origin	Use BSAs of non-animal origin	Use BSAs of non-animal origin	Use chemical fertilizers	Use chemical fertilizers	Use chemical fertilizers
Use chemical fertilizers	Use chemical fertilizers	Use chemical fertilizers	Use chemical fertilizers	Use chemical fertilizers	Wait 0 days	Wait 45 days	Wait 90 days
Wait 9 months	Wait 0 days	Wait 90/120 days	Wait 6 months	Wait 12 months	Change application method	Change application method	Change application method
Stop growing covered produce	Stop growing covered produce	Stop growing covered produce	Stop growing covered produce	Stop growing covered produce			
Change application method	Change application method	Change application method	Change application method	Change application method			

(Subpart I) Standards directed to domesticated and wild animals (proposed §§ 112.81 to 112.84)

This subpart draws a distinction between the potential for contamination to occur from domesticated animal excreta (feces) in situations when domesticated animals are permitted to graze or work where covered produce is grown prior to harvest as well as the contamination that may occur from wild animal feces at any time when covered produce is grown, prior to harvest.

Domesticated animals include livestock, working animals, pets, and domesticated animals from a nearby area (such as livestock from a nearby farm).

Baseline agricultural conditions

In its Draft QAR (2013c), FDA concluded that the following agricultural practices or pathways for pathogenic transport, relative to wild and domesticated animals, are important causes of contamination of produce:

- Animals can be a source of contamination to produce.
- Animal excreta pose a high likelihood of contamination of produce.
- Excreta from domesticated animals pose a greater likelihood of contamination of produce than does excreta of wild animals. However, domesticated animals can be expected to be more readily controlled (*i.e.*, kept apart from produce growing, harvesting, and postharvest areas).
- Excreta from wild animals that rarely associate with human activities poses the least likelihood of contamination of produce.
- Human pathogens from animal excreta—once introduced to the growing environment—can be expected to eventually die off, but the rate of die-off is dependent upon a number of environmental, regional, and other agro-ecological factors.

Grazing by domesticated animals may occur under circumstances where working animals are in the fields where covered produce is grown either pre-harvest or during harvest; when a covered activity takes place in an outdoor area or a partially enclosed building and when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce; or when a covered activity takes place in an outdoor area or a partially enclosed building if, under the circumstances, there is a reasonable probability that animals will contaminate covered produce because it is reasonably likely that such animals will encroach on such areas and deposit excreta on covered produce or food contact surfaces.

The threat from domesticated animal fecal contamination does not occur entirely within the produce field. Contamination may also occur from domesticated animal waste that is left uncontrolled and may infiltrate agricultural water systems; therefore, any areas where animal waste or litter is stored must be kept separate from where covered activities occur. For example, STEC has been shown to be viable in cattle water trough sediments for up to 245 days; in addition, contaminated trough water that has had no known animal contact for six months has been demonstrated to infect cattle (LeJeune et al., 2001). Where such reservoirs of contaminated water may infect animals and may potentially be located in close proximity to covered produce or where

covered activities occur, it is evident that pathogen persistence and colonization present risk factors for contamination of covered produce.

In its Draft QAR, FDA found that the number and type of pathogens detected in animal feces varies with the animal species (FDA, 2013c), as addressed below.

The predominant source of STEC from animal feces is cattle, and the predominant source of Salmonella spp. from animal feces is poultry (Cramer, 2006; McSwane et al., 1998; WHO, 2006). Cattle are also well-known carriers of different types of pathogens, including strains of *Salmonella enterica* and (non-STEC) pathogenic *E. coli* (Goulet et al., 2012; Todd et al., 2007). Beyond cattle and poultry, other domesticated animals such as sheep, goats, and swine are also common carriers of pathogenic microorganisms (Sadowsky and Whitman, 2011).

Domesticated animals (Franz et al., 2008; Renter and Sargeant, 2002) and pests (*e.g.*, rats) are generally more likely to harbor zoonotic pathogens than are wild animals, due to their closer proximity to and interaction with humans (Nielsen et al., 2004).

Wild animals, including pests, can also act as reservoirs of human pathogens (Fischer et al., 2001; Jay et al., 2007). Pathogenic *E. coli* have been isolated from deer, feral swine, pigeons and seagulls (Fischer et al., 2001; Jay et al., 2007; Nielsen et al., 2004). Dunn et al. reports that the prevalence of STEC infection in white-tailed deer ranges from a level that is undetected to 2.4 percent (2004).

Wild animal intrusion presents hazards from fecal contamination of covered plants directly, or indirectly by contaminating agricultural water or soil. Fecal contamination of plants and watersheds following wild or feral animal intrusion may be considered a risk factor for pre-harvest produce contamination (Jay-Russell, 2013).

As noted in the PS PR, consistent with section 419(a)(1)(A) of the FFDCA (21 U.S.C. § 350h(a)(3)(D)), and in accordance with FSMA, FDA consulted with the USDA NOP and USDA's NRCS, USFWS, and EPA to ensure that environmental and conservation standards and policies established by those agencies were appropriately considered in developing the requirements proposed in subpart I. FDA tentatively concluded that the provisions of proposed subpart I do not conflict with or duplicate the requirements of the NOP.

In addition, in the supplemental proposed rule, FDA added proposed § 112.84 to explicitly state that proposed part 112 would not authorize or require covered farms to take actions that would constitute the "taking" of threatened or endangered species in violation of the ESA, or require covered farms to take measures to exclude animals from outdoor growing areas, or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

Similar to the standards proposed for agricultural water and BSAs of animal origin, there are some growers association standards that do have guidelines for controlling risk factors related to domesticated and wild animals contaminating crops. Additionally, USDA NRCS Conservation Practice Standards are often employed by growers to help control pests and to minimize risk of contamination where food is grown and livestock is managed on the same facility.

Other Considerations

FDA received several comments to the supplemental proposed rule and the Draft EIS regarding the provisions of subpart I. Some of these comments included questions or concerns about the proposed waiting period (proposed § 112.82) and proposed provisions for animal intrusion (proposed § 112.83). FDA is presently considering these and other comments, which may result in amendments in the relevant provisions of any final rule that may result. At this time, FDA does not consider any potential amendments to result in additional environmental or related socioeconomic impacts beyond what is assessed in this Final EIS. If amendments are made, FDA will explain its rationale behind those amendments in the Final Rule. Any cost-related impacts would be described in detail in an accompanying FRIA, and any related environmental impacts would be summarized in the ROD.

Grazing: Alternative I. As proposed (alternative that will best fulfill FDA's statutory mission and responsibilities, § 112.82)

At a minimum, if animals are allowed to graze or are used as working animals in fields where covered produce is grown, and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, the grower must take the following measures: (a) An adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed to ensure the safety of the harvested crop; and (b) If working animals are used in a growing area where a crop has been planted, measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce.

In addition, proposed § 112.84 would explicitly state that proposed part 112 does *not* authorize or require covered farms to take actions that would constitute the "taking" of threatened or endangered species in violation of the ESA; require growers to take measures to exclude animals from outdoor growing areas; or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. See the Chapter 4 subsection for *Resource components not included for review in the EIS*.

Grazing: Alternative II. Waiting period of 9 months

As an alternative, FDA is proposing that if animals are allowed to graze or are used as working animals in fields where covered produce is grown and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, the grower must employ (1) a minimum waiting period of 9 months between the time grazing or working animals are present in areas where covered produce is grown and the time such produce is harvested from such growing areas and (2) measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce.

This alternative is consistent with the originally proposed provisions for the use of raw (untreated) manure as a BSA of animal origin, described in § 112.56(a)(1)(i) from the 2013 proposed rule.

FDA's provision regarding the protection of habitat and species protected under the ESA would be carried forward to this alternative. However, it would not include the statement that the measure does not require measures to exclude animals from outdoor growing areas.

Grazing: Alternative III. Waiting period of 90 days and 120 days

If animals are allowed to graze or are used as working animals in fields where covered produce is grown and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, the grower must employ minimum waiting period of 90 days and 120 days before harvest, depending upon whether the edible portion of the crop contacts the soil (as specified in 7 CFR 205.203(c)(1)).

FDA's provision regarding the protection of habitat and species protected under the ESA would be carried forward to this alternative. However, it would not include the statement that the measure does not require measures to exclude animals from outdoor growing areas.

Animal Intrusion: Alternative I. As proposed (alternative that will best fulfill FDA's statutory mission and responsibilities, §§ 112.83 and supplemental proposed § 112.84)

FDA proposed that if under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce, the grower must monitor those areas that are used for a covered activity for evidence of animal intrusion:

(1) As needed during the growing season based on:
  (i) The covered produce; and,
  (ii) The grower's observations and experience; and,
(2) Immediately prior to harvest.

If animal intrusion, as made evident by observation of significant quantities of animals, animal excreta or crop destruction via grazing occurs, the grower must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112 (proposed § 112.83(a) and (b)).

Prior to the publication of the 2013 proposed rule, there were a few instances in which a foodborne illness outbreak resulted in growers taking extreme measures to exclude wildlife from their crops (*e.g.*, clear-cutting land adjacent to farm fields), in large part due to food-safety practices imposed by buyers. These measures ultimately resulted in substantial environmental impacts to water quality, riparian (wetland) habitat, and the elimination of wildlife on and near farm land (Lowell et al., 2010). Upon publication of the 2013 proposed rule, some members of industry expressed concern of a repeat of this or similar action taken on a nationwide scale. Specifically in relation to proposed § 112.83 and in response to concerns raised about potential adverse consequences to habitat as a result of the 2013 proposed rule, FDA, in the supplemental proposed rule, added § 112.84, which states:

> Nothing in this regulation authorizes the "taking"[39] of threatened or endangered species as that term is defined by the Endangered Species Act (16 U.S.C. 1531–1544) (*i.e.*, to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), in violation of the Endangered Species Act. This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

FDA furthered clarified in the preamble to the supplemental proposed rule that growers of produce should also be aware that clearing or manipulation of habitats, including activities affecting water resources, groundwater or natural vegetative cover, can affect species listed as threatened and endangered. The supplemental proposed rule further stated that growers can identify whether any listed species may be present in their area by checking USFWS's Endangered Species Web site and the Information, Planning, and Conservation System Web site; that growers should coordinate with their local USFWS office on any activity that could potentially affect listed species or critical habitat;[40] and growers could contact their local USFWS office for additional information. See Chapter 4 for additional information on this issue.

Animal Intrusion: Alternative II. Animal exclusion

If there is a reasonable probability that animal intrusion will contaminate covered produce, under this alternative FDA would require that the grower monitor these areas as needed during the growing season, based on the covered produce being grown and the growers observations and experiences (proposed § 112.83(a)(1)(i) and (ii)), and immediately prior to harvest (proposed § 112.83(a)(2)). If animal intrusion is reasonably likely to occur, the grower must take measures to exclude animals from fields where covered produce is grown.

In addition, proposed § 112.84 would explicitly state that proposed part 112 does not authorize or require covered farms to take actions that would constitute the "taking" of threatened or endangered species in violation of the ESA, although it would not include the statement that the measure does not require measures to exclude animals from outdoor growing areas, or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

Management decisions

Table 2.1-6 lists a set of management decisions that a grower may make if the PS PR were finalized with one of the specified alternatives. The environmental impact of these decisions is addressed in Chapter 4.

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[39] In the Endangered Species Act, "take" means "to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct" (16 U.S.C. 1532(19)). USFWS has further declared that "harm" includes "significant habitat modification or degradation" (64 Fed. Reg. 60727-31, November 8, 1999). Thus, the habitat as well as the endangered animal is protected from private action.

[40] As defined under the ESA, critical habitat is a specific geographic area that contains features essential for the conservation of a threatened or endangered species and that may require special management and protection (see 16 U.S.C. 1532(5)(A)).

The management decisions would be different for grazing operations as compared to the requirements FDA proposes for monitoring and managing animal intrusion. For all alternatives under domesticated animal grazing, FDA and USDA determined that reasonably foreseeable management decisions growers may make include fencing (although it is more likely that fencing may not involve the produce field; rather, it involves better managing the fences that may already exist to manage livestock in dual purpose operations) and/or observing an adequate waiting period. Waiting periods include what is believed to be consistent with current practices (immediately prior to or during harvest), waiting nine months (similar to Alternative I under subpart F / Untreated BSAs of animal origin), or waiting 90 or 120 days (consistent with USDA organic regulations for applying raw manure).

For all alternatives under animal intrusion, FDA and USDA determined that reasonably foreseeable management decisions growers may make include that the grower may not harvest the field or part of the field that is contaminated with animal fecal matter or that the grower may take measures to exclude wildlife. Under normal circumstances this may include hunting or trapping wildlife, but under some unspecified circumstances this may mean to consider fencing the farm field where covered produce is grown.

Table 2.1-6. Management decisions, by alternative proposed under subpart I

Domesticated / Grazing			Animal Intrusion	
Alternative I. Adequate waiting period	**Alternative II. Waiting period of 9 months**	**Alternative III. Waiting period of 90/120 days**	**Alternative I. Not harvest crops that may be contaminated**	**Alternative II. Measures to exclude wildlife**
Fencing	Fencing	Fencing	Do not harvest field or part of field	Do not harvest field or part of field
Adequate waiting period	Adequate waiting period	Adequate waiting period	Measures to exclude wildlife, *e.g.*, fencing, trapping, hunting, poisoning	Measures to exclude wildlife, *e.g.*, fencing, trapping, hunting, poisoning

(Subpart A) General Provisions (proposed §§ 112.1 to 112.6)

FDA proposes three main size classifications of businesses in relation to the PS PR. The size classifications clarify whether and to what extent businesses would be subject to the provisions of the PS PR, if finalized. The size classifications of businesses (farms or farm mixed-type facilities) include not covered (excluded), very small businesses, and small businesses (Table 2.1-7). While no specific classification was established in the PS PR, farms that do not fit into these size classifications would be considered "large."

In the 2013 proposed rule, FDA proposed to apply the Produce Safety regulation only to farms and farm mixed-type facilities with an average annual monetary value of food (as defined under the FFDCA and including seeds and beans used to grow sprouts) sold during the previous 3-year period of more than $25,000 on a rolling basis (proposed § 112.4). FDA also proposed to apply

certain monetary value thresholds based on total food sales to define those very small and small businesses that would be eligible for FDA's proposed extended time periods to comply with the Produce Safety regulation. In the original proposed § 112.3(b)(1), FDA proposed to define "very small business" to mean a business that would be subject to proposed part 112 and for which, on a rolling basis, the average annual monetary value of food (as defined under section 201(f) of the FFDCA and including seeds and beans used to grow sprouts) sold during the previous 3-year period is no more than $250,000. In addition, under original proposed § 112.3(b)(2), FDA proposed to define "small business" to mean a business that is subject to proposed part 112 and for which, on a rolling basis, the average annual monetary value of food (as defined under section 201(f) of the FFDCA and including seeds and beans used to grow sprouts) sold during the previous 3-year period is no more than $500,000, and which farm is not a "very small business."

In the supplemental proposed rule, FDA amended proposed § 112.4 and the definitions of very small business and small business in proposed § 112.3(b) to apply the monetary value thresholds based on sales of produce, rather than on total food sales. Accordingly, farms or farm mixed-type facilities with an average annual monetary value of produce (as "produce" is defined in proposed § 112.3(c)) sold during the previous 3-year period of $25,000 or less (on a rolling basis) would be excluded from coverage of the Produce Safety regulation. In addition, "very small business" and "small business," which would be subject to the Produce Safety regulation but under extended compliance periods, would be determined based on sales of produce, rather than on total food sales.

Table 2.1-7. Summary of three size-based categories of businesses under the PS PR

Size class of farm/business	Average annual monetary value	Potential Exemptions
Small Business	Above $250,000 and no more than $500,000 in produce sales	Specified extended compliance periods.
Very Small Business	Above $25,000 and no more than $250,000 in produce sales	Specified extended compliance periods.
Not covered	$25,000 or less in produce sales	Excluded from coverage under the PS PR.

In addition, FDA proposed certain criteria for when certain businesses may be eligible for a qualified exemption from provisions of the PS PR and, instead, would be subject to certain specified modified requirements (see proposed §§ 112.5 and 112.6). This distinction is important to some impact-related analyses in Chapter 4. Under the PS PR, in order for farms to be eligible for qualified exemptions, farms would need to meet the following proposed requirements: (i) The farm must have "food" sales averaging less than $500,000 per year during the previous 3-year period preceding the applicable calendar year; and (ii) the farm's sales to qualified end-users must exceed sales to other buyers during that period. A qualified end-user is either (a) the consumer of the food or (b) a restaurant or retail food establishment that is located in the same State as the farm or not more than 275 miles away.

Farms eligible for a qualified exemption would be largely exempt from the proposed provisions of the PS PR but would be subject to a narrower set of modified requirements. As defined in subpart R, proposed §§ 112.201 to 112.213, FDA would have the authority to withdraw the qualified exemption under certain circumstances, and farms would be able to have the exemption re-instated under certain other circumstances.

Other Considerations

FDA received several comments to the supplemental proposed rule and the Draft EIS in relation to the provisions of subpart A. Some of these comments included questions or recommendations on, among other topics, FDA's proposal not to cover farms with less than 25,000 in annual produce sales and our proposed compliance periods. FDA is presently considering these and other comments, which may result in amendments in the relevant provisions of any final rule that may result. At this time, FDA does not consider any potential amendments to result in additional environmental or socioeconomic impacts beyond what is assessed in this Final EIS. If amendments are made, FDA will explain its rationale behind those amendments in the Final Rule. Any cost-related impacts would be described in detail in an accompanying FRIA, and any related environmental impacts would be summarized in the ROD.

Alternative I. $25,000 threshold (alternative that will best fulfill FDA's statutory mission and responsibilities; proposed § 112.4(a))

Under this alternative, a farm or farm mixed-type facility[41] with an average annual monetary value of produce (as defined in proposed 21 CFR 112.3(c)) sold during the previous 3-year period of more than $25,000 (on a rolling basis) would be a "covered farm" subject to part 112, and a ''covered farm'' subject to this part would be required to comply with all applicable requirements of this part when conducting a covered activity on "covered produce" (proposed 21 CFR 112.4).

Farms with an average annual monetary value of produce sold of $25,000 or less collectively account for 4 percent of covered produce acres,[42] suggesting that they contribute little exposure to the overall produce consumption within the United States (FDA, 2014b). According to 2012 NASS data, there are 2,103,210 total farm operations in the United States, of which approximately nine percent, or 189,637 farms, grow produce (USDA NASS, 2014a). Of the farms that grow produce, nearly 69 percent, or 130,204 farms, have less than $25,000 average annual monetary value of produce sold and would be eligible for a qualified exemption under the PS PR (FDA, 2014b).

Of the 189,637 farms that grow produce, an estimated 18.7 percent, or 35,503 farms, grow covered produce, which represents approximately 1.70 percent of all farms.

FDA further proposed flexibility in complying with any final rule that results from the proposed rule. The proposed effective date for the final rule would be 60 days after the date of publication

[41] A full definition of the term "farm" and "mixed-type facility" is in the glossary. See also § 112.3 of the PS PR.
[42] This accounts for roughly 3.1 percent of all produce acres in the U.S.

of the final rule in the *Federal Register*, with staggered compliance dates depending upon the size of the business operations (Table 2.1-8).

Table 2.1-8. Compliance dates for businesses of various sizes if a final rule is implemented

Size class of farm/business	Compliance dates following the Final Rule	**Total:** includes additional 2 years for compliance with water quality provisions**
Very small businesses	4 years	6 years
Small businesses	3 years	5 years
All other covered businesses	2 years	4 years

* Consistent with section 419(b)(3)(B) of the FFDCA.
** Increased flexibility in accordance with the PS PR

Alternative II. $50,000 threshold

Under this alternative, farms with $50,000 or less of annual value of food sold would be excluded from coverage of the PS PR. FDA estimated within its 2013 PRIA that approximately 11,958 fewer farms would be covered by the rule if this threshold for annual revenue were selected (FDA, 2013b). These estimates were derived on the basis of the originally proposed § 112.4(a) using the monetary value threshold based on total "food" sales. However, FDA amended the proposed provision in its supplemental proposed rule to apply the monetary threshold based on sales of produce. In the accompanying supplemental PRIA (FDA, 2014b), FDA determined that regulating on the basis of the average annual monetary value of "produce" sold reduces the burden to small businesses. FDA did not quantify the associated number of covered and excluded farms using the $50,000 threshold based on produce sales; however, the number of farms eligible for a qualified exemption under a threshold based on total value of produce sold could be no lower than the amount of farms eligible for a qualified exemption based on the total value of food sold.

At the $50,000 threshold, because more farms would potentially be excluded, even fewer foodborne illnesses would be prevented (1.69 million annually based on 2013 estimates) than what would be expected at the $25,000 threshold, and the illness-related expenditures nationwide would increase over what is expected at the $25,000 threshold. The total estimated annual cost for compliance nationwide is estimated at $348 million, which is lower than what is expected when compared to the $25,000 threshold (Alternative I of this provision).

Alternative III. $100,000 threshold

Under this alternative, farms with $100,000 or less of annual value of food sold would be excluded from coverage. FDA originally estimated that at this threshold, 20,071 fewer farms would be covered by the PS PR; as with Alternatives I and II, the numbers were prepared based on the value of food sold, rather than the value of produce sold. Potentially even fewer farms would be covered as compared to Alternative II.

FDA anticipates at this threshold that even fewer illnesses attributable to produce (1.63 million annually) would be prevented as compared to the threshold values of Alternatives I and II. The potential annual illness-related costs would be higher because fewer farms would be covered. However, the total estimated annual compliance costs would be lower ($316 million).

Alternative IV. $25,000 threshold (covered produce only)

Farms with $25,000 or less of annual value of covered produce sold would be excluded from coverage. There are no data available to distinguish between farms at this threshold selling total produce as compared to those selling only covered produce; however, the number of farms that would be covered could be no higher than, and would almost certainly be slightly lower than, that of Alternative I. Therefore, the amount of potential prevented illnesses and costs to comply with the PS PR would likely be comparable to the slight (unestimated) differences between total produce and covered produce.

Table 2.1-9 provides a summary of estimated costs and benefits for each of the alternatives identified under subpart A.

Table 2.1-9. Summary of alternatives compared under subpart A

	≤ $25,000 total produce (Alternative I)*	≤ $50,000 total food (Alternative II)**	≤ $100,000 total food (Alternative III)**	≤ $25,000 covered produce (Alternative IV)
Covered Farms	35,503	28,253	20,140	Slightly fewer than Alternative I
Excluded (non-covered) farms	130,204	161,384	169,497	Slightly greater than Alternative I
Prevented Illnesses (millions)	1.73 **1.57***	1.69	1.63	Slightly fewer than Alternative I
Total domestic benefits (millions)	$930.00***	$1,004	$973	Slightly fewer than Alternative I
Total domestic costs (millions)	$386.23	$348	$316	Slightly fewer than Alternative I

*As updated in the supplemental PRIA (FDA, 2014b). Other estimates are found in the original PRIA (FDA, 2013b).
**These numbers were based on estimates within the 2013 PRIA (FDA, 2013b).
***While this figure for total domestic benefits suggests that total domestic benefits under Alternative I would be lower than the benefits derived under Alternatives II or III, we note that this apparent discrepancy results from the fact that different data sets were used to estimate costs and benefits in the 2013 PRIA and the 2014 supplemental PRIA. As explained in the text describing each individual alternative, we expect total domestic benefits from Alternative I to be the highest.

Management decisions

Table 2.1-10 lists a set of management decisions that a grower may make if the PS PR were finalized under each of the alternatives. The environmental impacts of these decisions are addressed in Chapter 4.

For all alternatives, FDA and USDA determined that the most reasonably foreseeable management decision the grower may make would be either to comply with the PS PR or to switch to a non-covered crop. FDA acknowledges that complying with the PS PR would to some extent mean complying with whichever alterative was selected, and further may depend upon the management decision that a grower might make under those alternatives. The analysis in Chapter 4 draws a comparison between all alternatives identified for potentially significant provisions and their associated potential management decisions, and summarizes these potential environmental and associated socioeconomic impacts in Chapter 4.7.

Table 2.1-10. Management decisions, by alternative proposed under subpart A

Alternative I. As Proposed. $25,000 or less average annual monetary value of produce sold are excluded	Alternative II. Farms with $50,000 or less average annual monetary value of food sold are excluded	Alternative III. Farms with $100,000 or less average annual monetary value of foodsold are excluded	Alternative IV. Farms with $25,000 or less average annual monetary value of covered produce sold are excluded
Comply with the rule	Comply with the rule	Comply with the rule	Comply with the rule
Switch to non-covered crops	Switch to non-covered crops	Switch to non-covered crops	Switch to non-covered crops

No Action Alternative

The baseline agricultural conditions as they relate to the potentially significant provisions of the PS PR are discussed in the preceding sections and are summarized within this section. Background environmental conditions by resource component evaluated in this EIS are provided in Chapter 3.

(Subpart A) General Provisions (Scope of the PS PR)

Several growers associations exist throughout the country to improve market value for their members and to promote sustainable growing conditions and food safety initiatives. Such initiatives maintain a level of competitiveness with other similar market providers.

Farms of all size classes participate in growers associations and similar market forums. Similarly, farms and businesses of all sizes participate in all types of markets. As previously discussed in Chapter 1.7, local produce markets, while previously dominated by local small farmers, have been trending toward a small amount of large farms owning a greater percentage of the total market share. While large farms make up a small percentage of the nation's total farms, large farms operate greater than 81 percent of the total produce growing acreage and also bear a greater risk of contributing to pathogen transport based upon the higher volume of produce that large farms contribute to the overall market.

(Subpart E) Agricultural Water

Regarding agricultural water, there are no federal regulations that require a specific microbial standard for maintaining relatively clean water supplies for irrigation purposes or that ensure that clean water used for other agricultural purposes remains relatively free of harmful pathogens. In 2012, EPA updated its recreational water quality standard to an STV of 410 CFUs per 100 ml water generic *E. coli* and a GM of 126 CFU per 100 ml in any 30 day interval; further, under the updated standards, there should not be greater than a ten percent excursion frequency of the selected STV magnitude in the same 30 day interval. This standard does not apply to agricultural water quality.

Agricultural water quality standards for produce growers are presently in place across the country. These standards are not uniform in their basic standard values. All states have drinking water quality standards, but few states have standards that specifically address agriculture or that are readily made available on state environmental or state agricultural Web sites.

The USDA GAP&GHP audit program promotes FDA guidance to industry on irrigation water quality and uses a process to certify and audit farms that are approved under the program to employ water quality standards. The GAP&GHP audit program offers guidance on water quality testing, water use, and surveillance for hazards associated with microbial risk factors; however, the program does not establish specific water quality standards.

Many growers associations provide standards for meeting water quality and work to reduce microbial risk factors. For example, the California Leafy Greens Marketing Initiative established standards for pre-harvest water in requiring California growers to analyze for generic *E. coli*, with acceptable levels not to exceed 126 MPN/100 ml (GM of five samples) and no more than 235 MPN in 100 ml of water for all single samples. Regarding post-harvest water, the California Leafy Greens Marketing Initiative requires its growers to analyze for generic *E. coli*, with acceptable levels not to exceed 126 MPN in 100 ml (GM of five samples), and no more than 576 MPN in 100 ml of water for all single samples. Table 2-1 provides additional examples of growers association standards.

Water quality conditions nationwide (addressed in Chapter 3.1) are the result of many factors—including geology, hydrogeology, topography, weather and climate—and may be influenced by human activities, animals, and natural processes. Water quality of surface waters generally are thought to be influenced more by contaminant sources than is groundwater, but even groundwater is subject to contamination from surface water bodies and run-off. Groundwater drawn from the same surface geographical location, but from different depths and bedrock layers, will many times vary in the level or concentration of microbes present.

The application of agricultural water for irrigation will vary by such factors as the type of crop being grown, location, climate, and water availability. Therefore, two farms that are adjacent to one another may employ two or more very different modes of irrigation.

(Subpart F) BSAs of animal origin

At present, a small percentage of farms—approximately 12.8 percent—use untreated BSAs of animal origin on their fields. Most BSAs of animal origin that are used on covered crops are treated before applying them to areas where covered produce is grown, in order to meet marketing agreements or growers association standards promoting food safety. Although this represents a relatively small percentage of farms, under today's conditions, BSAs of animal origin that are applied raw or applied treated but that used an inadequate treatment method still contribute to an estimated 244,917 illnesses annually.

Application intervals

There are varying standards at present guiding the intervals between application of BSAs of animal origin and harvest of the crop. Some standards are more specific, while others are more general. Many such standards only provide guidance on the time of year of application or the relative quantity of application based on soil and crop nutrient needs (discussed in more detail in Chapter 3.4). Many of these industry or state standards are defined in order to improve crop management and minimize environmental impacts to water quality. Examples of industry or federal (USDA) application to harvest criteria include national organic regulations, California (and similar) leafy greens marketing agreements, and the tomato food safety audit protocol (see Table 2.1-1).

USDA organic regulations

Roughly three percent of the food sold in the U.S. is USDA Certified Organic. The USDA ERS reports that only one percent of U.S. farms are certified organic (USDA ERS, 2013a). The USDA Certified Organic Program does not require a waiting period for treated BSAs (compost) application before harvest. USDA organic regulations require a waiting period for untreated BSAs of animal origin of 90 days (approximately three months), or 120 days (approximately four months) depending on whether the edible portion of the crop has direct contact with the soil.

California Leafy Greens Marketing Agreement

When applying raw (untreated) manure to fields where raw manure has been applied previously, this agreement requires a one-year waiting period before planting any variety of leafy green crops. With respect to treated (composted) BSAs, if microbe levels are below corresponding action level numbers, then an application interval of at least 45 days before harvest must be observed. For BSAs that are heat-treated with a process that requires validation, the grower shall observe an application interval of at least 45 days before harvest; for processes that are previously validated, no application time interval is required.

Tomato food safety audit protocol

Only properly composted (treated) manure is allowed for use in tomato fields and greenhouses due to the high potential for microbial contamination and transport.

(Subpart I) Domesticated and Wild Animals

State nutrient management guidelines and marketing or growers association standards related to fecal contamination from domesticated animal grazing or animal intrusion are not well defined.

Many state nutrient management plans generally offer time-of-year guidelines with respect to grazing and are oriented toward nitrogen contribution to soils (adding nutritive value) and minimizing run-off, rather than incorporating a harvest interval to minimize microbial safety-related hazards. In other words, grazing is managed through many state guidelines as a mode to augment soil conditions. Animal intrusion or pest management is not defined in most state management plans.

USDA organic regulations in 7 CFR § 205.239(e) provide that a "producer of an organic livestock operation shall manage livestock manure in a manner that does not contaminate crops, soil, or water by plant nutrients . . .." Other regulation standards revolve around grazing practices and management. USDA national organic regulations do not address animal intrusion protocols.

2.2 Provisions and alternatives considered but dismissed from detailed analysis

This Final EIS carries forward for evaluation FDA's proposed action of finalizing provisions of the PS PR and takes a hard look at a number of alternatives for potentially significant provisions defined in Chapter 1.2 as those provisions that FDA has determined may significantly affect the quality of the human environment. In determining whether or not an alternative is reasonable, and thus, carried forward for analysis, each identified alternative is evaluated against the stated Purpose and Need (Chapter 1.4). The potentially significant provisions include subpart A, subpart E, subpart F, and subpart I (Chapter 2.1).

FDA also proposed in the PS PR standards that we have determined would not result in any significant environmental impacts on the human environment. Standards that are not expected to result in significant impacts are identified and eliminated from detailed study (40 CFR 1501.7(a)(3)). The proposed standards that are dismissed from detailed analysis include subparts C, D, K, L, M, N, O, P, Q, and R (discussed in greater detail below). For purposes of this Final EIS, however, we are considering how these standards would contribute to our review of the "Socioeconomics and Environmental Justice" resource component when combined with other alternatives as part of the overall cumulative impact analysis (Chapter 5).

Finally, there are alternatives FDA identified early in the scoping process that did not meet the purpose and need of the proposed action, or that were not feasible for reasons associated with cost. These are potential alternatives that were eliminated from further review (see below).

Proposed Standards dismissed from detailed analysis

FDA has determined that the following alternatives are consistent with the classes of actions found in 21 CFR 25.30(h) and (j), General Categorical Exclusions, which include Current Good

Manufacturing Practice (CGMP) regulations;[43] Hazard Analysis & Critical Control Points (HACCP) regulations;[44] establishment standards;[45] emergency permit control regulations;[46] Good Laboratory Practice (GLP) regulations;[47] and issuance or denial of permits, exemptions, variances, or stays under these regulations, and procedural or administrative regulations. FDA has previously determined that these classes of actions do not have a significant impact on the human environment.

These proposed standards would establish a systematic approach to the identification, assessment of risk, and control of the food safety hazards associated with a particular food production process. Further considerations used when dismissing these proposed standards from further analysis are discussed under the relevant standards.

(Subpart C) Standards directed to personnel qualifications and training for personnel who handle (contact) covered produce or food-contact surfaces (proposed §§ 112.21 to 112.30).

Ensuring that personnel who operate or work for covered businesses are appropriately trained in safe practices that effectively reduce the risk of contamination of covered produce does not have a significant effect on the human environment. Training is a normal and customary part of employment for all types of professions. It is assumed that new employees would require training, and henceforth may require re-training in order to use new agricultural techniques, equipment, or best practices; therefore, training may occur in order to identify and minimize risks associated with microbial contamination. For many agricultural businesses of all sizes that belong to growers associations or are a part of marketing agreements that incorporate food safety practices, including growers of sprouts, a certain amount of personnel training may already be required. Generally, the major changes as a result of requirements aimed at training and qualification are an increase in recordkeeping and classroom-based training, which would not result in any significant environmental impact. While such training may require travel in some situations such as to attend workshops or bring in consultants with specialized knowledge and training, the overwhelming majority of the training will happen on site. Any environmental impacts that could be associated with the cost of the training is part of the overall cost-benefit analysis, which is considered in the context of the cumulative impact analysis in Chapter 4.7.

(Subpart D) Standards directed to health and hygiene (proposed §§ 112.31 to 112.33).

Adequate health and hygiene measures are a food safety staple for any business that handles food for human consumption. While such practices are not uniformly administered or consistently

[43] Information on CGMP regulations is found at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm090016.htm.
[44] Information on HACCP regulations is found at http://www.fda.gov/Food/GuidanceRegulation/HACCP/.
[45] Information on FDA Establishment Standards is found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=600&showFR=1&subpartNode=21:7.0.1.1.1.2.
[46] Information on emergency permit control regulations is found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=108.
[47] Information on FDA GLP regulations is found at http://www.21cfrpart11.com/files/library/pred_rules/mcdowall_glp_annotate.pdf.

followed in many industries, such measures are needed and can be codified to address good hygienic practices for activities covered under the PS PR. Actions covered under this provision, such as avoiding contact with animals while conducting covered activities, washing hands, using clean, single-service towels to dry hands, and maintaining sanitary conditions are everyday practices that do not result in significant environmental impacts. Many of these practices are also covered in industry guidance or guidelines for producers of covered produce.

(Subpart K) Standards directed to growing, harvesting, packing, and holding activities (proposed §§ 112.111 to 112.116).

Adequate clean and sanitary food contact surfaces on the farm or post-harvest facility are needed to ensure the safe production of produce while achieving microbial hazard reduction. Whether in an agricultural setting, at a market, or in the kitchen of a restaurant, clean, food-contact surfaces and sanitary practices are paramount to minimizing microbial contamination and are necessary to safeguard consumer health. Numerous state health regulations require clean, safe, and pest-free environments in which food is handled and prepared.[48] While such state health regulations do not necessarily extend to farms and farm mixed-type facilities, there is ample industry guidance for growers to avoid harvest-related activities for food that may be contaminated with animal feces. Because these actions are associated with common food industry practices that are among the classes of actions which FDA has previously determined do no result in significant environmental impacts, these actions are not expected to result in significant environmental impacts.

(Subpart L) Standards directed to equipment, tools, buildings, and sanitation (proposed §§ 112.121 to 112.140).

Adequate clean and sanitary equipment, tools, containers, buildings and facilities, and vehicles are needed to ensure the safe production of produce meant for human consumption, while achieving microbial hazard reduction. Similar food industry practices as will be required under the PS PR, if finalized, are required and carried out every day for consumer food establishments such as restaurants and supermarkets, and safe and sanitary conditions for these establishments are regulated primarily by state health regulations. In addition, in the agricultural setting, several voluntary and mandatory marketing agreements (*e.g.*, California Leafy Greens Marketing Agreement, T-GAPs) require similar standards for their participants. For many produce growers such practices are already normal and customary such that significant changes in industry practices would not be needed; therefore, Subpart L is not expected to result in significant environmental impacts.

[48] Where pests are present and where the situation may require pesticides, insecticides, or rodenticides to rid the environment from such pests, EPA-registered products are normally available for use. EPA requires an extensive environmental and human health risk review of such products prior to their gaining approval for registration. Such products should be handled in accordance with product labeling requirements to avoid adverse human health or environmental impacts.

(Subpart M) Standards directed to sprouts (§§ 112.141 to 112.150)

FDA estimates that 285 sprout operations may be affected by the rule nationwide (FDA, 2013b). According to surveys conducted by FDA (2012), approximately 67 percent of sprouting operations use municipal water that is treated for a zero detection limit for enteric viruses in accordance with the SDWA (40 U.S.C. § 300f et seq.) and that further meets the proposed requirement described under §§ 112.44(a) and 112.45(a)(1) and (2). Water used and discarded by all sprouting facilities is required to be discharged in accordance with National Pollutant Discharge Elimination System (NPDES) permits. Sprout facilities are believed to currently be largely, if not entirely, located indoors; and FDA's 1999 Sprout Guidance recommends that growing containers be located off of floors and away from walls to reduce the possibility of contamination by rodents, pests, or other animals. Also, sprouting facilities do not operate activities that require a clean air permit in accordance with the Clean Air Act of 1970 (CAA) (42 U.S.C, §7401 et seq.), do not typically use BSAs of animal origin, and generally use only controlled soil types or are hydroponic (soil-free). Furthermore, most sprouting facilities follow FDA's 1999 Sprout Guidance, which provides recommendations for reducing the risk of raw sprouts serving as a vehicle for foodborne illness. Many of the recommendations in FDA's Guidance for Industry are carried forward in FDA's proposed rule.

Sprouting operations are already highly regulated for water use and disposal or discharge, already rely heavily on existing municipal water sources, and many sprout operations currently follow FDA Guidance for Industry recommendations. Thus, the proposed FDA regulations under subpart M are not expected to result in significant environmental impacts on environmental resource components, such as water, soil, or biological and ecological resources.

(Subpart N) Analytical methods (proposed §§ 112.151 to 112.152).

Scientific-based analytical methods to facilitate accurate quality testing for the presence of harmful microbes have been approved or recommended by many agencies (federal and state) under specific circumstances and for specific microbes. Certain analytical methods or techniques have proven, over time, to be more accurate than others in identifying if a contamination problem is present. Testing guidelines generally have specific standards and conditions to ensure quality, and to ensure that proper equipment and/or sample disposal techniques are followed. Testing measures are taken every day by federal, state, and local agencies, industry groups, and private entities for a number of reasons. While there may be an increase in the number of tests performed by covered farms under the requirements that would be established under subpart N, such tests are expected to happen in certified laboratories, which are permitted facilities (must obtain permits for discharges to air, water, and for handling and disposing of hazardous materials in accordance with all applicable federal, state, and local regulations). Certified laboratories are also audited regularly by EPA-certified state and third-party auditors.[49] If the testing method (for *E. coli*) requires the use of hazardous materials, EPA requires the laboratory to comply with the applicable regulations for

[49] For example, laboratories that analyze drinking water compliance samples for coliform bacteria must be certified by EPA to perform coliform sampling in accordance with 40 CFR § 141.21.

neutralizing and disposing of the samples and materials used (this is specified in the EPA published document for whichever method the laboratory uses).[50]

Because the testing and disposal process is tightly controlled and regulated, FDA does not expect activities under subpart N to result in significant environmental impacts. Any potential environmental impacts associated with the cost of testing requirements are addressed as part of subpart E.

(Subpart O) Requirements applying to records that must be established and kept (proposed §§ 112.161 to 112.167).

Though compliance with the provisions set forth in subpart O of the PS PR could require that farms maintain additional records of their activities, and though there has been some public comment during the EIS scoping process that such recordkeeping may increase the use of paper products nationwide, FDA does not believe that the use of paper for recordkeeping is needed or would substantially offset the nationwide decline in use of paper products.[51]

Records may also be kept electronically so long as they are retrievable from an onsite location. Furthermore, to the extent paper is used, it may be recycled or it may be disposed of in the users' normal trash. FDA does not expect activities under subpart O to result in adverse environmental or social impacts.

(Subpart P) Variances (proposed §§ 112.171 to 112.182).

Variances may be requested by submitting to FDA a citizen petition using the process described in 21 CFR 10.30, specifically identifying the standard or standards from which the requesting entity is requesting a variance and identifying the specific growing conditions and science-based procedures or practices that would support a variance. For example, these variances may include variance from the requirements established in proposed § 112.44(c) when agricultural water is used during growing operations for covered produce (other than sprouts) using a direct water application method, variance from the process conditions established in § 112.54(c)(1) for static composting, and/or variance from the process conditions established in § 112.54(c)(2) for turned and treated composting. FDA expects requests for variances to be supported by relevant and scientifically valid information or materials specific to the covered produce or covered activity to support the petitioner's determination that the variance requested is reasonably likely to ensure that the produce is not adulterated and to provide the same level of public health protection as the relevant requirement. This would include information about the crop, climate, soil, and geographical or environmental conditions of a particular region, as well as the processes, procedures, or practices followed in that region.

[50] EPA Test Methods may be found at http://www.epa.gov/region1/info/testmethods/.

[51] The U.S. Department of Commerce's Reports on Manufacturers' Shipments, Inventories and Orders (September 2014 and 2013) demonstrate an overall decline in the manufacture and demand for paper products nationwide (paper products are not specified by type).

Proposed §§ 112.171 to 112.182 set forth the procedures for requesting a variance and FDA's review of such request. Establishing the administrative procedures for variances is the same type of action FDA considered when establishing the categorical exclusion in 21 CFR 25.30(h) concerning the issuance of administrative regulations, including procedures for submission of applications for approval that the agency has determined do not have a significant effect on the human environment. The variance procedures include requirements related to who may request a variance, what must be included in a request, the public availability of the information, who may respond to the request and how, scope of permissible variances, and criteria or procedures for denial, modification, or revocation of a variance. Administrative procedural requirements such as these do not have a significant effect on the human environment. However, an FDA action to grant or deny a particular variance request would be independent from FDA's action to establish the procedural requirement in a final produce safety rule. A decision by FDA to grant or deny a variance request would be a "major Federal action" (as defined in 40 CFR 1508.18). Therefore, FDA would evaluate, independent of any final rule on establishing administrative procedures for variances, its obligations under NEPA for a decision to grant or deny a particular variance request submitted consistent with such required procedures. Therefore, FDA does not need to consider environmental impacts related to the proposed administrative procedural requirements for variances in the Final EIS.

(Subpart Q) Compliance and enforcement (proposed §§ 112.191 to 112.193).

Provisions regarding compliance and enforcement are not expected to have a significant impact on the human environment. Considerations relating to the environmental impacts stemming from provisions with which individuals would need to comply under the PS PR, if finalized, are discussed in other sections of this document.

(Subpart R) Withdrawal of qualified exemption (§§ 112.201 to 112.213).

Consistent with section 419(f)(3)(A) of the FFDCA and proposed § 112.201 of the PS PR, FDA may withdraw a qualified exemption applicable to a covered farm under one of two circumstances: (1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the farm that had received a qualified exemption (proposed § 112.201(a)); or (2) if FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at the farm (proposed § 112.201(b)). However, in these cases, FDA is committed to working with farms directly. Depending on the circumstances, FDA may take a variety of actions, including educating growers and sending warning letters, as well as enforcement actions such as administrative detention, seizure, and injunction, to protect the public health and prevent or mitigate a foodborne illness outbreak. FDA may consider taking such actions prior to or in conjunction with a consideration to withdraw a qualified exemption. To make its intent clear that FDA would consider other actions, as appropriate, before issuing an order to withdraw a qualified exemption, FDA proposed § 112.201(b) in the supplemental proposed rule. In addition, under proposed § 112.213, FDA proposed to provide the process under which FDA would reinstate a qualified exemption that was withdrawn.

Establishing the administrative procedures for the withdrawal or reinstatement of qualified exemptions is the same type of action FDA considered when establishing the categorical exclusion in 21 CFR 25.30(h) concerning the issuance of administrative regulations, including procedures for submission of applications for approval, that the agency has determined do not have a significant effect on the human environment.

Other Considerations

FDA received several comments to the 2013 proposed rule, the supplemental proposed rule, and the Draft EIS in relation to these provisions of the PSPR. FDA is presently considering these and other comments, which may result in amendments in the relevant provisions of any final rule that may result. At this time, FDA does not consider any potential amendments to result in additional significant environmental impacts beyond what is assessed in this Final EIS. If amendments are made, FDA will explain its rationale behind those amendments in the Final Rule. Any cost-related impacts would be described in detail in an accompanying FRIA, and any related environmental impacts would be summarized in the ROD.

Potential alternatives that were eliminated from further review

In its Draft QAR, FDA performed an assessment of potential routes of contamination and the likelihood of contamination on farms (FDA, 2013c). FDA evaluated the relative risk for 12 different classes of commodities during growing, harvest, and post-harvest. Contaminated water is a potential route of contamination when directly applied during irrigation, when applied for protection during growing, and when indirectly applied. Soil amendments were another identified route of contamination during the growing process. Workers, animals, and equipment were also identified as potential routes of contamination during growing. FDA identified water, workers, and equipment as potential routes of contamination during harvest. Water, workers, equipment, and buildings were identified as potential routes of contamination during postharvest activities. All of these routes are being evaluated for standards to reduce the potential for biological contamination and associated risk of foodborne illnesses.

Procedures, processes and practices in each of these on-farm routes of contamination have the potential to introduce biological hazards into or onto any covered produce. Therefore, FDA proposed an integrated approach to prescribe standards for each of these on-farm routes of contamination (see 78 Fed. Reg. 3504 at 3524-3529). These standards are the foundation that FDA used to establish requirements for the growing, harvesting, packing, and holding of produce for human consumption, in order to minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. This is the purpose of FDA's proposed action (see Chapter 1.2). FDA is mandated to perform this action in accordance with FSMA (see Chapter 1.1). Alternatives or actions that FDA considered that did not meet the purpose of FDA's proposed action or were unreasonable were eliminated from further review.

FDA considered a number of options and alternatives that were based on industry, agency, and public comment for the proposed rule (see Chapter 1.8), as well as the analysis FDA conducted as part of its Draft QAR (FDA, 2013c) and PRIA and supplemental PRIA (FDA, 2013b and 2014b, respectively). The options and alternatives FDA considered but eliminated include:

(1) No new regulatory action.

FDA considered under this option to rely on current guidance such as GAPs guidance and other commodity-specific guidance, voluntary adoption of some or all provisions of the proposed regulation, current or enhanced state and local enforcement activity to bring about a reduction of potential harm from adulterated foods, or the tort system, with litigation or the threat of litigation serving to bring about the goals of the proposed rule.

However, FSMA requires FDA to conduct rulemaking establishing produce safety standards. Moreover, FDA believes that these methods are unable to fully minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce. The advantage of this option is that there would be no costs to the produce industry, but the disadvantage is that there would also be no benefits in terms of illnesses prevented.

(2) Exclude commodities not associated with outbreaks from some or all of the provisions of the rule.

As discussed in greater detail in Chapter 1.6, FDA considered and rejected the option to develop a framework that (based solely on a history of outbreaks or illnesses associated with the commodity) would be applicable to individual commodities or classes of commodities. Foodborne illness outbreaks have regularly been associated with commodities that have previously not been linked to outbreaks; therefore, this approach carries the risk of failing to prevent future outbreaks. In addition, because only a small percentage of outbreaks are both reported and assigned to a food vehicle, outbreak data may not provide a complete picture of the commodities upon which FDA needs to focus to minimize current and future risk of illness. Furthermore, FDA's Draft QAR (2013c) identifies common on-farm routes of contamination, which are not commodity-specific.

(3) Require less-extensive standards.

FDA considered that several of the proposed provisions could be combined to provide a less extensive set of controls than what was proposed in the proposed rule. Certain prevention measures could be separated and put forth as stand-alone regulations. For example, provisions regarding agricultural water could be issued as a separate proposed rule. The various individual measures would, by themselves, generate lower costs than the integrated program outlined in the proposed rule.

As an alternative, FDA considered that certain provisions could be eliminated altogether, such that eliminating provisions for domesticated and wild animals and BSAs of animal

origin would reduce the cost of the proposed rule; however, potential benefits relating to a reduction in foodborne illnesses would also be reduced. FDA did not select this alternative because all requirements are important in reducing the level of contamination and human health burden associated with produce. Additionally, the likely reduction in costs from cutting these requirements would probably not outweigh the benefits of preventing foodborne illnesses.

(4) Apply a $10,000 limit to an average annual monetary value of "food" sold during the previous three-year period (FDA, 2013b).

FDA considered under this option to require that farms or farm mixed-type facilities with an average annual monetary value of food sold during the previous three-year period of more than $10,000 would be considered covered farms subject to the proposed rule. If we were to implement such a rule more farms—many of which were estimated to be very small farms—would be required to implement the standards outlined in the proposed rule. The result would be an approximately 16 percent increase in costs to very small farms over the estimates provided in the 2013 proposed rule, with only minor estimated annual benefits in terms of a reduction in foodborne illnesses that would result from lowering the threshold for covered farms. FDA has not selected this alternative because the anticipated costs outweigh the potential benefits from eliminating all illnesses associated with these farms. Similarly, any thresholds below $10,000, including removing the exemption altogether, would also not be a feasible alternative.

(5) Apply a $25,000 limit to an average annual monetary value of "food" as the threshold above which farms would be subject to the rule (79 Fed. Reg. 58434 at 58437).

FDA considered that farms with an average annual monetary value of food sold of $25,000 or less collectively account for 1.5 percent of covered produce acres, suggesting that they contribute little exposure to the overall produce consumption. Applying the $25,000 limit to an average annual monetary value of "produce," rather than food (see proposed § 112.4(a)), sold would account for an estimated total of 4 percent of covered produce acres and about 3.1 percent of all produce acres in the United States. The proposed rule would remove farms with produce sales of $25,000 or less from coverage, resulting in removal of an additional 2.1 percent of produce acres from coverage.[52] Under this scenario, as with the previous proposed approach, such businesses would not contribute significantly to the volume of produce in the marketplace that could become contaminated and, therefore, would have little measurable public health impact. FDA tentatively determined that applying the $25,000 limit to "produce" sales would not adversely affect the level of public health protection that it proposes to accomplish.

[52] After removal of acres as a result of the provisions related to the qualified exemption, produce that is rarely consumed raw, and produce destined for commercial processing that eliminates pathogens of concern.

(6) With respect to standards directed to agricultural water, no detectible *E. coli* per 100 ml (see Chapter 2.1 subpart E, and 79 Fed. Reg. 13593, March 11, 2014).

FDA considered an alternative to proposed § 112.44(c) (2013 proposed rule, 235 CFUs (or MPN) generic *E. coli* per 100 ml) that would equate to no detectible *E. coli* per 100 ml. Water generally associated with no detectible *E. coli* is municipally treated drinking water. Many farms across the U.S. are not presently connected to such municipal systems due to the rural setting for most agriculture (water treatment plants generally reach to residential and commercial users in suburban and urban settings). In addition, if farms were connected to municipal supplies, it is likely they would not be permitted to draw all agricultural water needed from those supplies for irrigation due to the very large water demand that irrigation requires (irrigation water demand from surface and groundwater is detailed in Chapter 3.1.3). Furthermore, there presently is no EPA-approved chemical treatment for contaminated water used to control pathogens in water directly applied to produce (EPA, 2014a) (see Chapter 4.2 for a more detailed discussion). Therefore, FDA determined that this alternative is not a reasonable option at this time.

Potential alternatives from commenters that were eliminated from further review

After publication of the Draft EIS, some commenters submitted additional alternatives for FDA to consider beyond those addressed in the Draft EIS. FDA's response to these comments is found in Appendix E. Based on its consideration of public comments, FDA did not add any new alternatives or potentially significant provisions for detailed analysis. The alternatives proposed in the public comments included that FDA consider removing the $25,000 threshold below which farms would be exempt from the rule. As discussed above, FDA has not selected the alternative of applying a threshold of $10,000 because the anticipated costs outweigh the potential benefits from eliminating all illnesses associated with these farms. Similarly, as stated above, we do not consider removing the threshold altogether would be a feasible alternative. Moreover, FDA stated in the supplemental proposed rule that applying the $25,000 limit to "produce" sales would not adversely affect the level of public health protection that it proposes to accomplish. Comments also suggested that FDA consider alternative standards for agricultural water including deferring promulgation of a water quality standard until further research can be conducted. The agricultural water standard is a key provision aimed at preventing foodborne illness. FDA's QAR addresses the reduction in foodborne illness that would be associated with this provision. Deferring promulgation of this standard would have significant detrimental effects on human health such that FDA would not be able to meet its stated purpose and need. Therefore, this alternative is not considered to be feasible.

Some commenters requested that FDA analyze the environmental impacts of developing a manure standard that accounts for application of biological soil amendments that fall between fresh manure and composted material, such as the application of aged manures. FDA considers aged manures to fall within the spectrum of untreated BSAs of animal origin. In order to establish an alternative for "aged" manure or "aged" BSAs of animal origin, FDA would need to be able to identify specific parameters under which the microbial load of pathogens would scientifically be proven to consistently provide a level of protection greater than BSAs of animal origin which are not aged. There is no scientific evidence available to show that the process of aging BSAs of animal origin

is sufficient to be safe without treatment nor to establish conditions under which that might be possible. FDA does not see aged manure offering different protections from the alternatives already proposed and considered. For this reason, a more flexible standard for biological soil amendments as proposed by the commenters, which may still result in a greater likelihood of pathogen transport, is not a reasonable alternative that meets the purpose and need of the proposed action.

2.3 Incomplete or unavailable information

Based on the scope of the EIS, as discussed in Chapter 1.9, this section describes the information that was not available for FDA to use to support a more detailed impact analysis on a regional or national level.

With respect to applying BSAs of animal origin, there are no consistent data available nationwide that identify the timing for applying untreated or treated soil amendments with respect to the produce commodity's growing and harvest intervals. Factors that influence timing of application include (but are not limited to) the commodity, climate or region, and availability and cost of the soil amendment(s). USDA organic regulations and certain mandatory or voluntary state- or commodity-specific marketing agreements may regulate application to harvest intervals, and to some extent they may regulate how a soil amendment is applied. But the conditions specific to growing seasons, soil amendment availability, and soil amendment application vary too widely by region and commodity to enable us to evaluate the environmental impact from applying treated or untreated BSAs on a regional or national basis. In the absence of this information, FDA determined in Chapter 4.3 that management decisions by farmers that are influenced by application intervals may reduce the amount of produce grown due to a reduced number of harvests per year. This may result in an increase in the price of certain produce if supply is reduced and demand is high. However, this effect is expected to be stabilized by market forces (*i.e.*, other growers within the same region, in other regions, or by international growers), which would fill any gaps in supply. Therefore, FDA does not anticipate significant environmental impacts from the use of treated or untreated BSAs of animal origin, regionally or nationally under certain alternatives.

The Socioeconomic and Environmental Justice evaluation (see background data in Chapter 3.7) relies primarily on U.S. Census block data as well as USDA NASS survey information specific to where covered produce is grown. While NASS data do provide the ethnicity (in most cases) of a farm's principal operator, these data sets do not provide the locations of covered farms by size class related to the principal operator's ethnicity. Therefore, FDA could not distinguish between a principal operator of any particular ethnicity that operates a farm with an average annual revenue of greater than $500,000 compared to a farm with an average annual revenue of less than $25,000 of produce sold. The EIS uses statistical analysis to identify the low-income and minority population percentage within any given state to establish a "meaningfully greater" threshold upon which to base an impact analysis by state and region. This approach is consistent with CEQ guidance, *Environmental Justice Guidance under the National Environmental Policy Act* (CEQ, 1997a). Regarding minority farmworkers, the EIS relies on data from the USDA ERS and the DOL on farmworker demographics and median income. Very limited data are available for minority

farmworkers for several reasons. First, both the USDA ERS and the DOL rely on surveys taken periodically. Furthermore, farmworker employment is often seasonal work and is sometimes filled by non-U.S. Citizens or farmworkers brought to the farms by third-party contractors. Finally, in the case of DOL surveys, survey data is only reported for California. Using the available data, FDA was able to evaluate potential impacts to certain low-income farmworkers populations and low-income principal operators. However, because coverage under the rule would be tied to monetary threshold of sales of produce, FDA expects the potential impacts related to compliance with the rule for very small and small farms (which are more likely to experience a greater level of impacts because of greater relative compliance costs) may be entirely mitigated to the extent these farms are eligible for a qualified exemption. Therefore, FDA does not reasonably anticipate significant adverse impacts to low-income farmworkers or low-income primary operators at a regional or national level (see Chapter 4.7).

FDA was able to identify minority farmworker populations and minority primary operators in certain regions. Potential impacts could be tied to the costs of compliance (particularly for farmers operating small and very small farms) that could result in the termination of farmworkers in areas where minority farmworker populations are higher (thus minority farmworkers in certain regions may be disproportionately impacted by the rule), or that could result from a farmer deciding to cease growing crops altogether. However, in light of the discussion above regarding the cost of compliance and the mitigating factors related to farms being eligible for qualified exemptions, FDA does not anticipate significant adverse impacts to minority farmworkers or minority primary operators.

Therefore, additional information on the locations of covered farms by farm size related to the principal operator's ethnicity and specific income level, or related to farmworker ethnicity and income level would allow for a more detailed level of analysis on a regional or national level. However, given the proposed provisions in the rule for a qualified exemption, FDA does not anticipate any farmworker terminations or farm closures to result in significant adverse impacts to low-income or minority populations at a regional or national level.

3.0 Affected Environment

This chapter is intended to identify the environmental resource components that may be influenced by the proposed action of implementing the PS PR. Before and as a result of the EIS scoping process, FDA identified eight resource areas for evaluation: 1) water resources; 2) biological and ecological resources; 3) soils; 4) waste generation, disposal and resource use; 5) air quality and greenhouse gases (GHGs); 6) cultural resources; 7) socioeconomics and environmental justice; and, 8) human health and safety.

This chapter is organized into subchapters that address each of the eight environmental resource components as recognized above. Each resource subchapter provides the following information:

1. Definition of the Resource. Definitions include the physiographic or geographic scope of the resource that is potentially affected, list the relevant existing laws or agencies that have purview over regulating the resource area, and establish the baseline conditions that exist before the PS PR is to be implemented so that the potential impacts were appropriately measured or estimated in the EIS.

2. Regulatory Oversight. Identifies the existing federal and state regulations (where applicable) pertaining to each environmental resource component.

3. Current Background Environmental Conditions. Data sources include scientific research; data compiled and presented by FDA or other regulatory agencies (including cooperating agencies); maps or figures developed by such agencies or maps and figures developed by the FDA contractor from data derived from authenticated sources; and tables and graphics used to better describe the resource background conditions.

3.1 Water Resources

3.1.1 Definition of the Resource

Water Resources encompasses the sources of water that are useful to plants, animals, and humans in a particular area. Changes in the environment can affect a hydrologic system's water quality, and the availability of usable water.

Resource use means how the resource is applied to crops in raw form (untreated), processed (chemically or physical filtration) or municipal (treated). The PS PR would regulate agricultural water used on covered commodities on produce farms. It would also regulate water used a) for irrigation during growing, prior to harvest; b) in cooling, packing, holding, and maintaining hydration (crispness/firmness); and, c) in washing produce, as well as water used for cleaning packing and packaging materials and for food contact surfaces. Each of those various uses would incur different water quality standards, measured by indicator bacteria (generic *E. coli* for all agricultural water).

In terms of identifying the background conditions of the resource, this section identifies the following factors:

- regulatory or industry practices that govern the use and protection of the resource;
- the natural environment of the resource;
- physical, chemical and biological anthropogenic stresses placed on the resource; and
- frequency and cause of impairments (current baseline conditions).

3.1.2 Regulatory Oversight

The CWA (33 U.S.C. § 1251 et seq.) is the principle law governing pollution control and water quality. The objective of the CWA is to restore and maintain the chemical, physical and biological integrity of the nation's waters (EPA, 2014b and c). The primary statutes relating to water resources also includes SDWA (42 U.S.C. § 300f et seq.). The SDWA assigns the EPA responsibility and authority to regulate public drinking water supplies by establishing national health-based drinking water standards to protect against both naturally-occurring and man-made contaminants (USDA ERS, 1994).

Section 402 of the CWA requires that municipal, industrial and commercial facilities that discharge into wastewater or stormwater directly from a point source (a pipe, ditch or channel) into a surface water of the U.S. (e.g., a lake, stream, or river) must obtain a permit under the NPDES permit (EPA, 2014d).[1]

Under Section 303(d) of the CWA, states, Territories, and certain tribes are required to develop lists of impaired waters (determined as impaired through testing regiments) (33 U.S.C. 1313(d)). CWA Sections 305(b) and 303(d) deal specifically with water quality assessments and Total Maximum Daily Load (TMDL) development (EPA, 2014e), which is used to develop national water quality criteria as a basis for State water quality standards (Section 305(b) is found at 33 U.S.C. § 1315). Under this regulation, if an operator or facility has a permit to discharge to surface water (e.g., in this case an entity such as a CAFO, sprouting facility, or other permitted agricultural operation that may be discharging to an impaired water body that is on the state's TMDL list) the entity may be held accountable to comply with its permit requirements.

The CWA requires states to designate beneficial uses for all waters and develop water quality standards to protect each use. Beneficial uses include drinking water as well as primary contact recreation, fish consumption and aquatic life support (EPA, 1998).

Water quality standards are set for maximum acceptable concentrations of pollutants in order to establish acceptable ranges for potential contaminants (USDA ERS, 1994). Water quality standards define (not quantify) conditions and attainable goals for a designated water use. Water quality standards (or criteria) may include; biological (desirable aquatic communities), nutrients (to prevent over-enrichment) and sediment (to avoid adverse effects) (EPA, 2014f).

[1] Relevant to this EIS, some farm operators, e.g., certain confined animal feeding operations (CAFOs), are also required to obtain and maintain a NPDES permit.

3.1.3 Current Background Conditions

3.1.3.1 Physical Processes and Environmental Setting

Water may be drawn from several different sources, such as groundwater, surface water, rain harvesting, or water storage. Some growers may have reasonable access to quite a few of these resources, while others have trouble obtaining sufficient access to even one source (such as in arid regions). Water availability and access depends upon a number of factors including, but not limited to, geology and hydrogeology, topography, climate and precipitation. It is important for growers to manage their water source effectively to experience a successful crop yield. Surface water and groundwater can both be used for irrigation, and are widely used in some areas to increase yields where natural precipitation is lacking during the growing season.

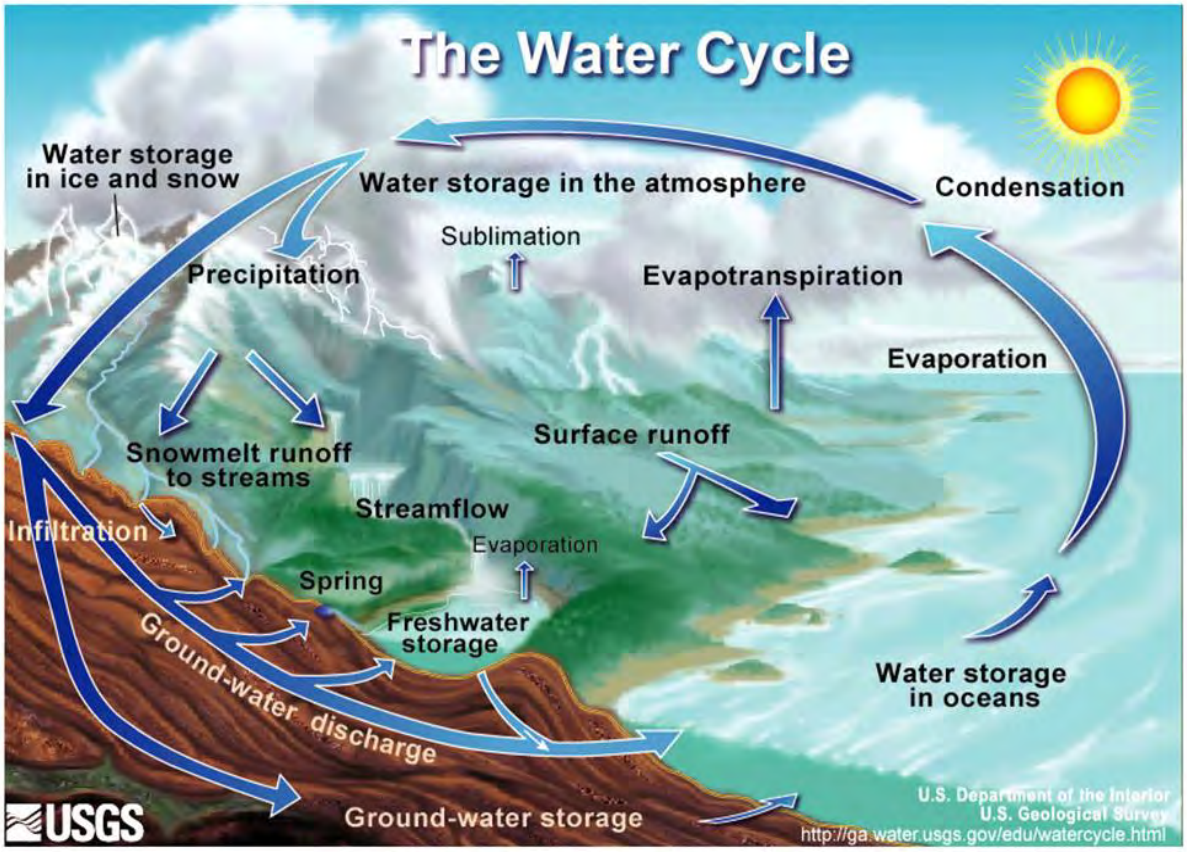
The USGS (2009) reports that surface water has historically been the primary source for irrigation, although trends identified in the 2009 report show an increasing usage of groundwater since the mid-20th Century (USGS, 2009). A 2005 water use summary published by USGS (2009) indicates that during 1950, 77 percent of all irrigation withdrawals were surface water. USGS notes that trends show that surface-water withdrawals comprised only 59 percent of the total. Groundwater withdrawals for irrigation during the early 21st Century were more than three times larger than during the mid-20th Century. About 61.1 million acres were irrigated in 2005 according to USGS. About 30.5 million acres were irrigated with sprinkler systems; 26.6 million acres were irrigated with surface flood systems, 4.05 million acres with micro-irrigation systems; and the national average application rate was 2.35 acre-feet per acre per year. Appendix B of this EIS explains the different types of agricultural irrigation used and describes the irrigation practices and considerations relevant to the produce covered under the PS PR.

Both surface water and groundwater can contain natural ambient innocuous bacteria, as well as enteric organisms indicating fecal material contamination. Water containing enteric organisms can contain pathogens, which are a risk to consumers, and such water used as agricultural water is therefore a concern. The PS PR would seek to limit the potential for harmful pathogens contaminating covered produce through agricultural water, including irrigation water.

3.1.3.2 The Hydrologic Cycle and Interactions of Groundwater and Surface Water

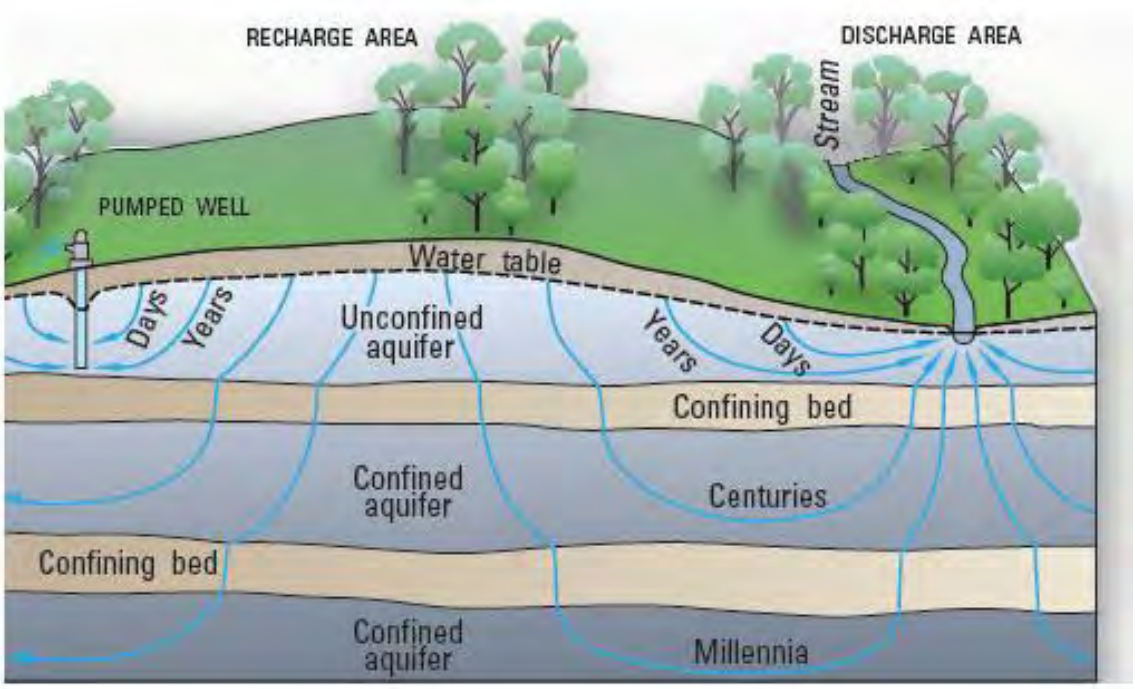
The hydrologic cycle, as explained by the USGS (1998), is the continuous movement of water above, and below the Earth's surface. Figure 3.1-1 is a simple diagram of the hydrologic cycle, which shows only major transfers of water between continents and oceans. However, there is a great deal of variability that contributes to hydrologic processes. Precipitation is the source of virtually all freshwater in the hydrologic cycle, but its distribution is highly variable (based on climate and other factors). Similarly, evaporation and transpiration return water to the atmosphere nearly everywhere, but evaporation and transpiration rates vary considerably according to climatic conditions. As a result, much of the precipitation never reaches the oceans as surface and subsurface runoff before the water is returned to the atmosphere. The relative magnitudes of the individual components of the hydrologic cycle, such as evapotranspiration, may differ significantly even at small scales, as between an agricultural field and a nearby woodland.

Figure 3.1-1. The hydrologic cycle



As shown in Figure 3.1-2, the direction and speed of groundwater movement is determined by characteristics of aquifers and confining layers of subsurface rocks (which water has a difficult time penetrating) in the ground. Water moving below ground depends on the permeability of soil and bedrock layers, and on the porosity (the amount of open space in the material) of the subsurface rock. If the rock has characteristics that allow water to move relatively freely through it, then groundwater can move greater distances in a number of days. But groundwater can also sink into deep aquifers where it takes thousands of years to move back into the environment, or even go into deep groundwater storage, where it might stay for much longer periods.

Figure 3.1-2. Groundwater flow paths and timeframes (USGS, 1998)



- Unconfined aquifers: In unconfined aquifers, water has simply infiltrated from the surface and saturated the subsurface material. If people drill a well into an unconfined aquifer, they have to install a pump to push water to the surface.

- Confined aquifers: Confined aquifers have layers of rock above and below it that are not very permeable to water. Natural pressure in the aquifer can exist; pressure that can sometimes be enough to push water in a well above the land surface. Not all confined aquifers produce artesian water; however, artesian pressure can force water to the surface with great pressure. (Note: this concept is important when considering potential impacts because if poor surface water quality causes additional groundwater pumping to supply irrigation needs, confined aquifers can become less pressurized and may need to be pumped or pumped from greater depths, which is more expensive.)

3.1.3.3 Surface Water Hydrology

Rivers are major aquatic landscapes for plants and animals. Rivers can help keep aquifers full of water by discharging water downward through their streambeds (USGS, 1998).

When looking at the location of rivers and the amount of streamflow in rivers, an important concept is the river's "watershed." A watershed encompasses the area of land that contributes to all of the water that falls within that area and is transported to the same place (e.g., a larger water body such as an estuary). Watersheds can be as small as a farm pond or large enough to encompass a water basin. Larger watersheds may contain many smaller watersheds. It depends

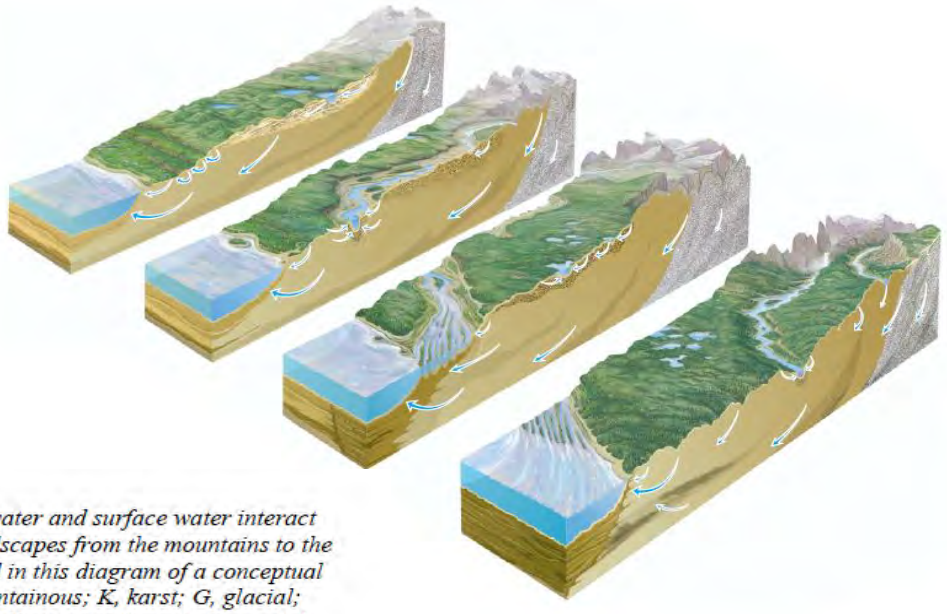
on the outflow point; all of the land that drains water to the outflow point is the watershed for that outflow location.

3.1.3.4 Surface Water/Groundwater Interactions

Figure 3.1-3 shows how streams interact with groundwater in all types of landscapes. With respect to understanding potential impacts to the availability and quality of water resources it is important to recognize that surface water and groundwater resources are interconnected (USGS, 1998). The interaction takes place in three basic ways: streams gain water from inflow of groundwater through the streambed (gaining stream, Figure 3.1-4), they lose water to groundwater by outflow through the streambed (losing stream, Figure 3.1-5), or they do both, gaining in some reaches and losing in other reaches. For groundwater to discharge into a stream channel, the altitude of the water table in the vicinity of the stream must be higher than the altitude of the stream-water surface. Conversely, for surface water to seep to groundwater, the altitude of the water table in the vicinity of the stream must be lower than the altitude of the stream-water surface.

Losing streams can be connected to the groundwater system by a continuous saturated zone (Figure 3.1-5) or can be disconnected from the groundwater system by an unsaturated zone. Where the stream is disconnected from the groundwater system by an unsaturated zone, the water table may have a discernible mound below the stream (Figure 3.1-6) if the rate of recharge through the streambed and unsaturated zone is greater than the rate of lateral groundwater flow away from the water-table mound. An important feature of streams that are disconnected from groundwater is that pumping of shallow groundwater near the stream does not affect the flow of the stream near the pumped wells. In some environments, streamflow gain or loss can persist; that is, a stream might always gain water from groundwater, or it might always lose water to groundwater. However, in other environments, flow direction can vary a great deal along a stream; some reaches receive groundwater, and other reaches lose water to groundwater.

Figure 3.1-3. Groundwater and surface water interactions in various landscapes (USGS, 1998)



Ground water and surface water interact throughout all landscapes from the mountains to the oceans, as depicted in this diagram of a conceptual landscape. M, mountainous; K, karst; G, glacial; R, riverine (small); V, riverine (large); C, coastal.

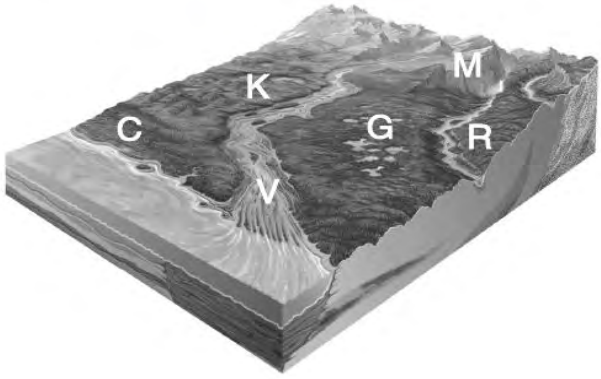


Figure 3.1-4. Gaining streams receive water from the groundwater system (USGS, 1998)

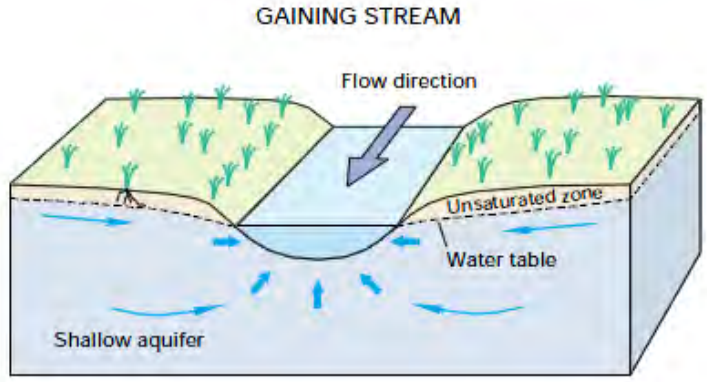


Figure 3.1-5. Losing streams lose water to the groundwater system (USGS, 1998)

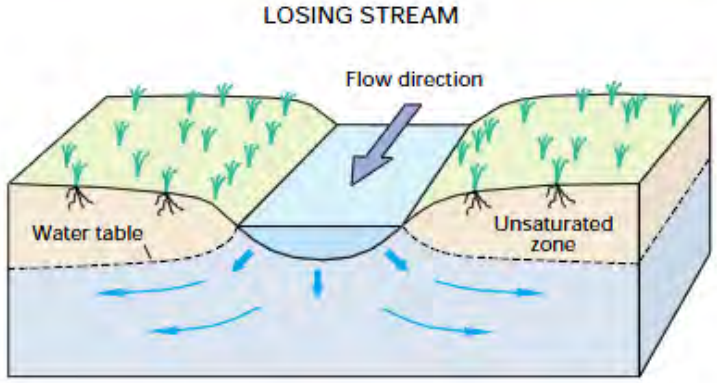
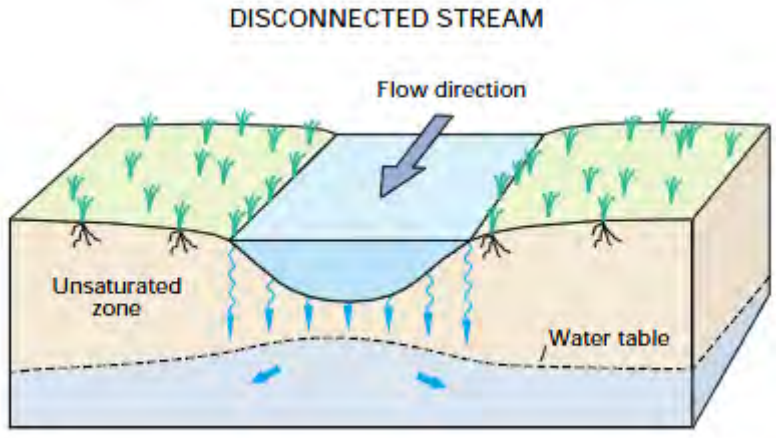


Figure 3.1-6. Disconnected streams are separated from the water table (USGS, 1998)



Changes in streamflow between gaining and losing conditions can also be caused by pumping groundwater near streams. Pumping can intercept groundwater that would otherwise have discharged to a gaining stream, or at higher pumping rates it can induce flow from the stream to the aquifer.

In addition to bank storage, other processes may affect the local exchange of water between streams and adjacent shallow aquifers. As described below, this interchange of water can also lead to the cross contamination of nitrates or pathogens between surface water and groundwater.

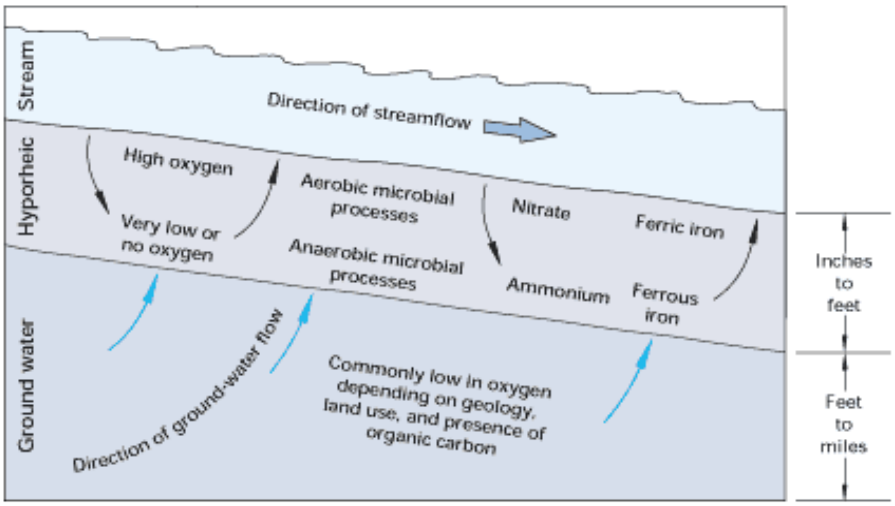
3.1.3.5 Chemical Interactions of Groundwater and Surface Water

As described in USGS (1998), groundwater chemistry and surface water chemistry cannot be dealt with separately where surface and subsurface flow systems interact. The movement of water between groundwater and surface water provides a major pathway for chemical transfer between terrestrial and aquatic systems (Figure 3.1-7). This transfer of chemicals affects the supply of carbon, oxygen, nutrients such as nitrogen and phosphorus, and other chemical constituents that enhance biogeochemical processes on both sides of the interface. This transfer can ultimately affect the biological (e.g., pathogens) and chemical (e.g., nitrates and pesticides) characteristics of aquatic systems downstream.

Many streams are impaired (contaminated); therefore, the need to determine the extent of the chemical reactions that take place in the region beneath and alongside a stream bed, where the mixing of shallow groundwater and surface water[2] is widespread because of the concern that the contaminated stream water will contaminate shallow groundwater. Streams offer good examples of how interconnections between groundwater and surface water affect chemical processes. Rough channel bottoms cause stream water to enter the streambed and to mix with groundwater in the hyporheic zone. This mixing establishes sharp changes in chemical concentrations in the hyporheic zone. A zone of enhanced biogeochemical activity usually develops in shallow groundwater as a result of the flow of oxygen-rich surface water into the subsurface environment, where bacteria and geochemically active sediment coatings are abundant (Figure 3.1-7). This input of oxygen to the streambed stimulates a high level of activity by aerobic (oxygen-using) microorganisms if dissolved oxygen is readily available. It is not uncommon for dissolved oxygen to be completely used up in hyporheic flow paths at some distance into the streambed, where anaerobic microorganisms dominate microbial activity. Anaerobic bacteria can use nitrate, sulfate, or other solutes in place of oxygen for metabolism. The result of these processes is that many solutes are highly reactive in shallow groundwater in the vicinity of streambeds.

[2] This region of mixing is called the hyporheic zone.

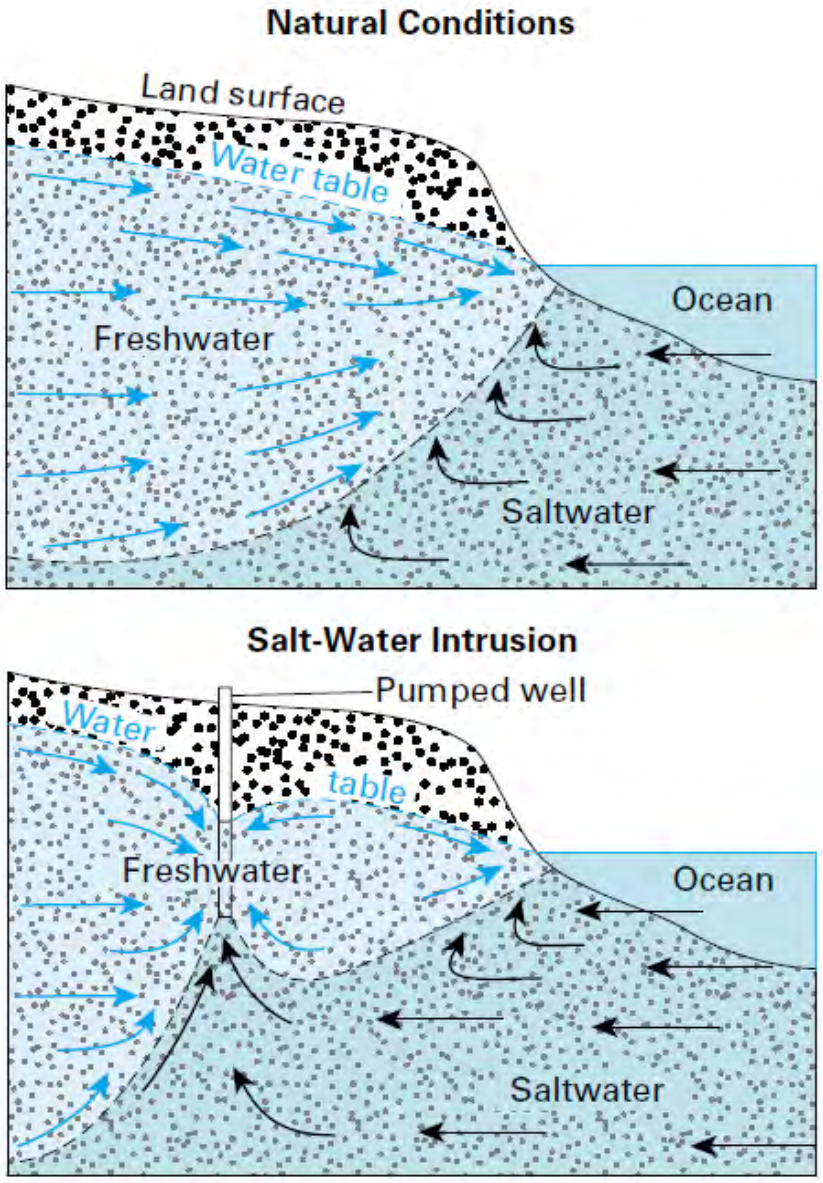
Figure 3.1-7. Processes and chemical transformations that may take place in the hyporheic zone (USGS, 1998)



3.1.3.6 Saltwater Intrusion

In some coastal areas, intensive pumping of fresh groundwater has caused salt water to intrude into fresh-water aquifers (Figure 3.1-8). Since saltwater has high concentrations of dissolved sodium chloride (salt) and other minerals, it can be hazardous to animals or plants in large concentrations (USGS, 2003a).

Figure 3.1-8. How intensive groundwater pumping can cause salt-water intrusion in coastal aquifers. (USGS, 2003a)

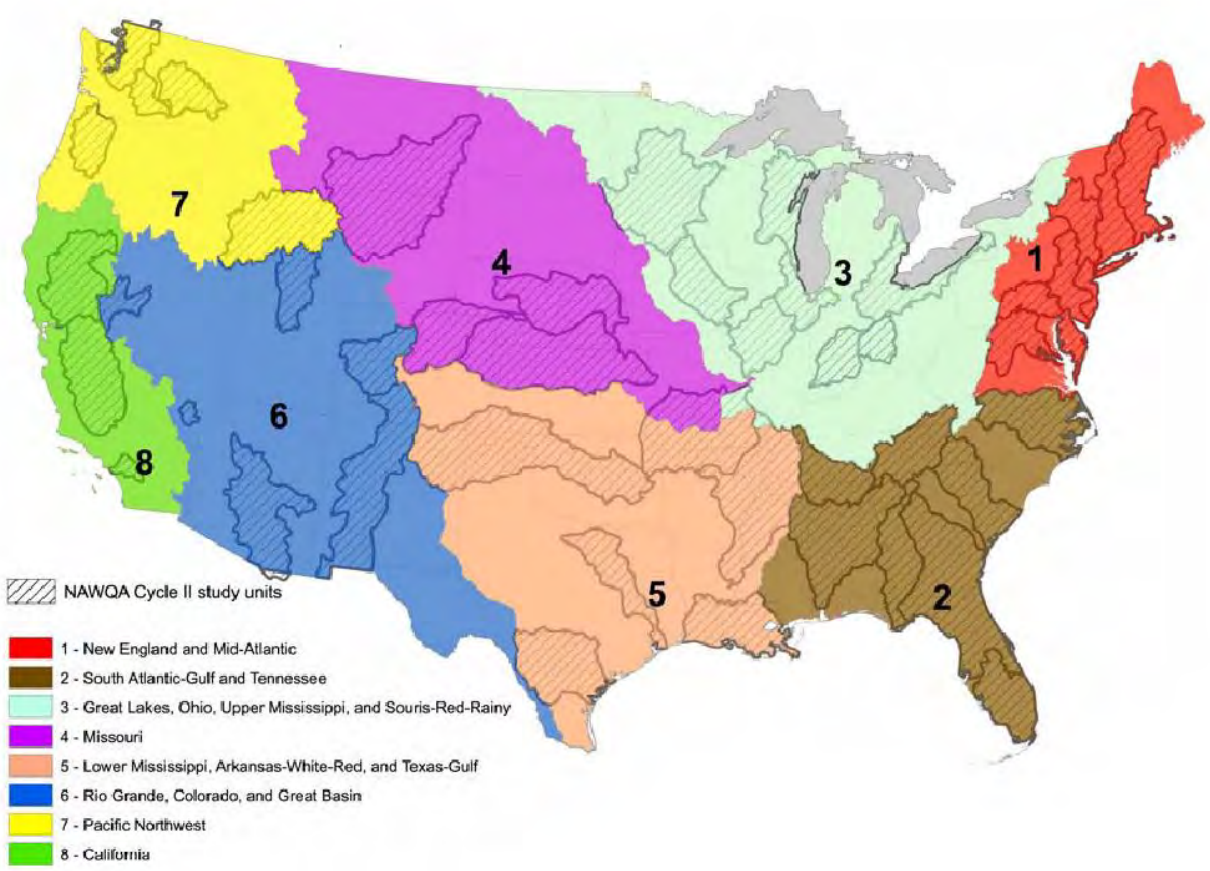


3.1.3.7 National Water-Quality Assessments

In 1991, the U.S. Congress established the National Water-Quality Assessment (NAWQA) Program within the USGS to develop nationally consistent long-term datasets and provide information about the quality of the Nation's streams and groundwater (USGS, 2010). As described by USGS, a major focus of NAWQA is on regional- and national-scale assessments of water-quality and trends in streams and rivers. NAWQA has identified eight large geographical regions (referred to as "major river basins") as the basis for its status and trends assessments. NAWQA assessments build upon previous findings generated from 1992-2001 for streams and rivers in smaller basins (referred to as "Study Units"). Primary goals remain the same: to

characterize the status of surface-water quality (stream chemistry and ecology); determine trends at those sites that have been consistently monitored for more than a decade; and build an understanding of how natural features and human activities affect water quality. Figure 3.1-9 illustrates the major U.S. river basins and sets the stage for the discussion of potential water quality impacts in Chapter 4.

Figure 3.1-9. Major river basins defined by NAWQA (USGS, 2006a)



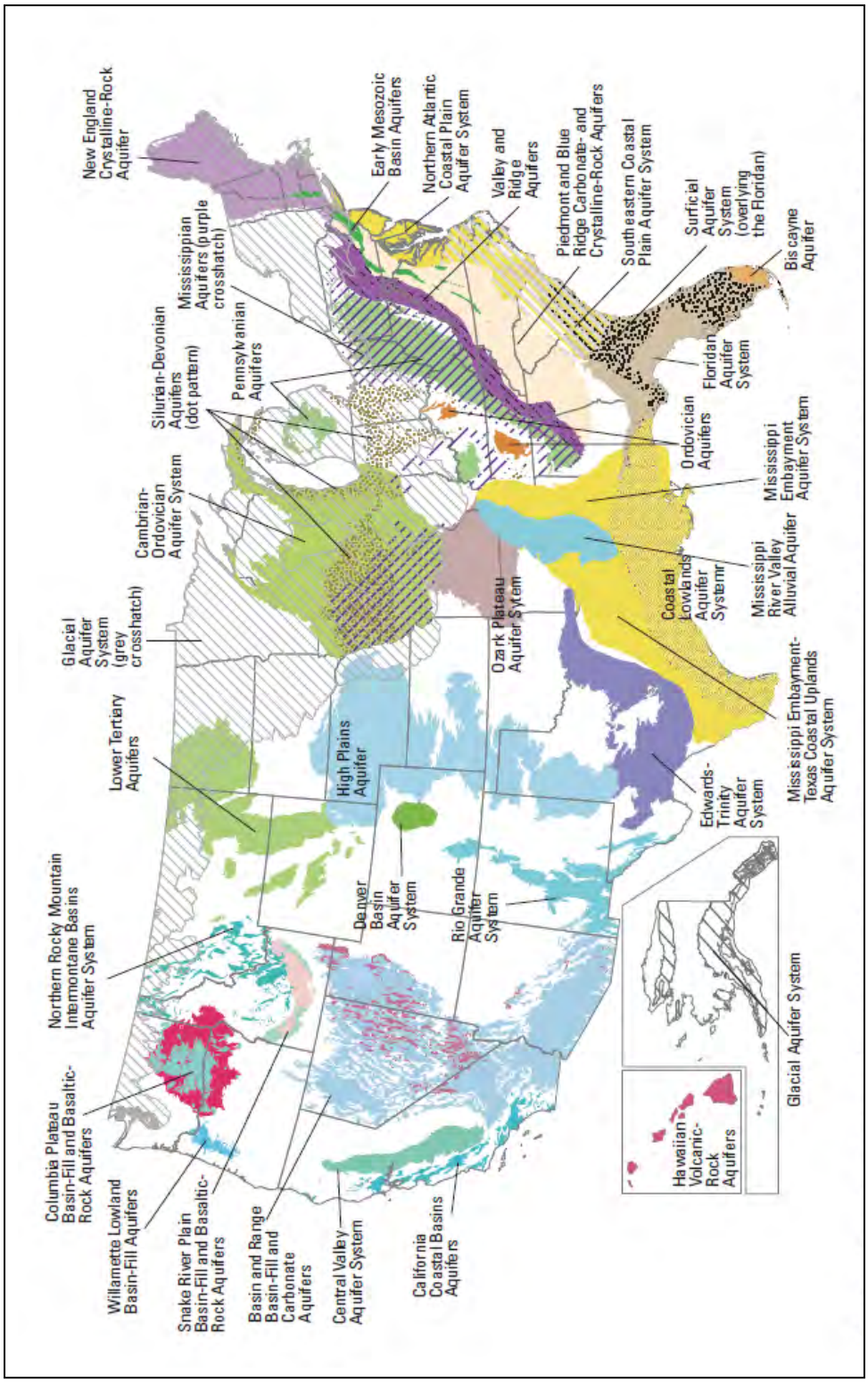
The USGS defines an aquifer as a geologic formation, group of formations, or part of a formation that contains sufficient saturated, permeable material to yield significant quantities of water to streams, wells and springs (USGS, 2014a). A total of 62 principal aquifers underlie the U.S. (USGS, 2010). Each principal aquifer is classified as one of six types of permeable geologic material: unconsolidated deposits of sand and gravel, semi-consolidated sand, sandstone, carbonate rocks, interbedded sandstone and carbonate rocks, or basalt and other types of volcanic rock. Each aquifer shown in Figure 3.1-10 is generally the uppermost principal aquifer.

Several aquifer resources (aquifer systems) are shared transboundary along the southern border of the United States and Mexico.[3] Examples include the Hueco Bolson aquifer that underlies the Rio Grande rift and extends from New Mexico to the El Paso-Ciudad Juarez geographic area of Texas, and also extends into Mexico (USGS, 2010); and the Santa Cruz and San Pedro aquifers that underlie portions of Arizona and Mexico (USGS, 2013a). The U.S. Congressional Research Service estimates that there are approximately 20 transboundary (also called binational) aquifers that underlie the U.S. and Mexico (Carter et al., 2015).[4] Several of these shared aquifers contribute to larger aquifer systems. Of the aquifer systems that are accessed in major produce-growing regions, and which may be experiencing drought or groundwater drawdown (compare Figure 3.1-10 with Figure 1.7-4 in Chapter 1.7), portions of the Edwards-Trinity aquifer system and the Basin and Range, Basin-Fill and Carbonate aquifers (or Alluvial Basins of Arizona) are shared transboundary with the Northeastern and Northcentral reaches of Mexico (compare Figure 3.1-10 with Figures 3.1-23 and 1.7-4 in Chapter 1.7). The Edwards-Trinity and Alluvial Basins of Arizona aquifer systems correspond with regions D, I, and J.

[3] We acknowledge that several aquifers are also shared across the northern border of the United States. However, as discussed elsewhere in this EIS, the regions along the northern border of the United States are not currently experiencing drought or significant groundwater drawdown. Therefore, further analysis about such aquifers is not included in this document, as impacts relating to any further groundwater drawdown would not rise to a significant level.

[4] Eckstein (2011) noted that other studies report the estimated number of shared aquifers vary and that additional studies and more accurate data are needed.

Figure 3.1-10. Location and extent of the principal aquifers in the U.S. as defined by NAWQA (USGS, 2010)

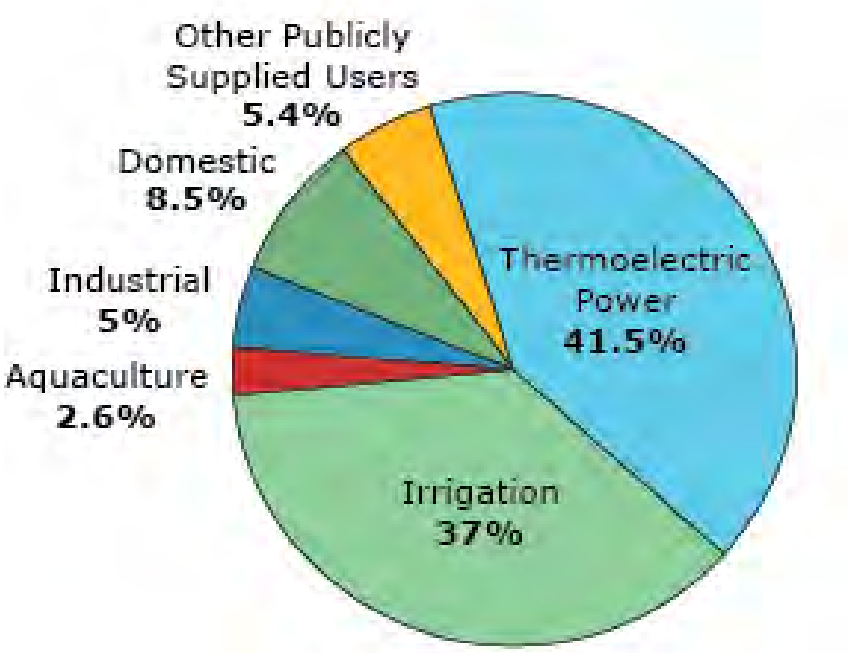


3.1.3.8 Total Water Use in the U.S.

Every five years since 1950, the USGS has published a series of estimated water use reports that include estimates of water withdrawals by state, source of water, and category of use (USGS, 2009). The twelfth report in the series is titled "Estimated use of water in the U.S. in 2005," and is the most recent report available. Unless otherwise cited, the information pertaining to water use in 2005 and presented below was obtained from the USGS report (USGS, 2009).[5]

Figure 3.1-11 shows the percentage of total U.S. water withdrawals by major user group. As of 2005, crop irrigation represented the second highest usage of water; although it should be noted that the figure does not distinguish between covered produce and all crops. Additional supporting information is found in Figure 3.1-12 and Figure 3.1-13.

Figure 3.1-11. Total U.S. withdrawals, 2005 (USGS, 2009)



The geographic distribution of total, surface-water, and groundwater withdrawals is shown in Figure 3.1-12. The total withdrawals for a state are, in part, a function of the size of the state—for example, a large state would have more irrigable land area and larger irrigation withdrawals than a small state if other factors such as climate, soils, and available water supply are the same. In 2005, more surface water than groundwater was withdrawn for all categories except self-supplied domestic, livestock, and mining. Of the 270,000 million gallons per day (MGD) fresh surface water withdrawals, more than one-half were for thermoelectric power, and more than one-fourth were for irrigation. The largest surface water withdrawals were in California, where irrigation was the largest use of fresh surface water.

[5] Report completion and data availability for the 2010 survey was not expected to be available until late 2014.

Nearly two-thirds of the fresh groundwater withdrawals in 2005 were for irrigation, and more than one-half of the groundwater for irrigation was withdrawn in just four states: California, Nebraska, Arkansas, and Texas. Irrigation was the largest use of fresh groundwater in 25 states. Nationwide, groundwater withdrawals for irrigation were about 3.5 times larger than groundwater withdrawals for public supply.

As illustrated in Figure 1.7-4 (Chapter 1.7), roughly over 80 percent of covered farms occur in regions B, C, D, and U, including; central and southern California, southwestern Arizona, south-central Florida and central Washington.

USGS found in 2005 that total irrigation withdrawals were roughly 128,000 MGD, or 144,000 thousand acre-feet per year, and irrigation withdrawals were 37 percent of total freshwater withdrawals and 62 percent of total freshwater withdrawals for all categories excluding thermoelectric power. Surface water accounted for 58 percent of the total irrigation withdrawals. About 61.1 million acres were irrigated in 2005.

About 26.6 million acres were irrigated with surface (flood) systems, 4.05 million acres with microirrigation systems, and 30.5 million acres with sprinkler systems. The national average application rate was 2.35 acre-feet per acre.

The geographic distribution of total, surface-water, and groundwater withdrawals for irrigation is shown in Figure 3.1-13. In 2005, the majority of withdrawals (85 percent) and irrigated acres (74 percent) were in the 17 conterminous Western states. The 17 Western states are located in areas where average annual precipitation typically is less than 20 inches and is insufficient to support crops without supplemental water.[6] Surface water was the primary source of water in the arid West and the Mountain states. California, Idaho, Colorado, and Montana combined accounted for 49 percent of the total irrigation withdrawals and 64 percent of surface-water irrigation withdrawals. Nearly 90 percent of the groundwater used for irrigation was withdrawn in 13 states, and each of these states withdrew more than 1,000 MGD (1,120 thousand acre-feet per year) of groundwater for irrigation in 2005. Among these 13 states, groundwater was the primary source for irrigation in Nebraska, Arkansas, Texas, Kansas, Mississippi, and Missouri.

Total irrigation withdrawals in both Eastern and Western states were smaller in 2005 than in 2000, but because the West accounts for such a large majority of the total, changes in those states have a greater effect on the total. Groundwater withdrawals increased slightly in the East, and surface water withdrawals declined in both the East and West. Total irrigated acres decreased in the West by 4 percent and increased in the East by 5 percent. In the West, acres irrigated by surface irrigation methods declined by 16 percent, and acres irrigated by sprinkler methods increased by 9 percent. Irrigated acres in the East increased for all type of systems; the largest percentage increase was in microirrigation systems.

[6] In accordance to USGS in this context, these Western States refer to all or parts of Arizona, California, Colorado, Idaho, Kansas, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Texas, Utah, Washington, and Wyoming.

Total irrigation withdrawals of 128,000 MGD for 2005 were almost 8 percent less than the estimated 139,000 MGD withdrawn during 2000. Surface-water withdrawals of 74,900 MGD in 2005 were 9 percent less than in 2000, when an estimated 82,400 MGD were withdrawn. Groundwater withdrawals of 53,500 MGD in 2005 were about 5 percent less than the 56,600 MGD withdrawn in 2000. Total irrigated acres in 2005 were 2 percent less than 2000. Acres irrigated with surface (flood) irrigation systems declined by 10 percent, from 29.7 million acres in 2000 to 26.6 million acres in 2005. Acres irrigated with sprinkler irrigation systems increased almost 7 percent, from 28.5 million acres in 2000 to 30.5 million acres in 2005.

Five states—California, Nebraska, Texas, Arkansas, and Idaho—accounted for 52 percent of total irrigated acreage. Nebraska, Texas, and California accounted for 41 percent of the irrigated acreage using sprinkler and microirrigation systems. California alone accounted for 65 percent of the irrigated acreage with microirrigation systems. Sprinkler and microirrigation systems combined were associated with more than 56 percent of total irrigated acreage.

Generally, application rates were greatest in the arid West and Mountain states where surface water was the predominant source of water used for irrigation, and surface (flood) application was the predominant method of irrigation. Massachusetts is the exception with the highest application rate in the U.S. (6.9 acre-feet per acre), likely due to water-management practices in the many cranberry bogs in that state. In Arizona and Idaho, application rates exceeded 5 acre-feet per acre. Many states that typically use large quantities of water for irrigation, such as California, Montana, Florida, Kansas, and Nevada, showed declines in application rates in 2005 compared to 2000.

During 2005, livestock withdrawals were an estimated 2,140 MGD, or 2,390 thousand acre-feet per year. Livestock withdrawals were less than one percent of total freshwater withdrawals and one percent of total freshwater withdrawals excluding thermoelectric power. Groundwater was the source for 60 percent of total livestock withdrawals. Estimated total livestock withdrawals for 2005 were eight percent less than in 2000.

The geographic distribution of total, surface water, and groundwater livestock withdrawals in 2005 is shown in Figure 3.1-14. Texas, California, Oklahoma, and North Carolina each used more than 125 MGD for livestock and accounted for 35 percent of total livestock withdrawals in 2005. Texas, North Carolina, Nebraska, California, Iowa, and Kansas each used more than 80 MGD of groundwater for livestock and accounted for 47 percent of groundwater withdrawals for this use. California, Oklahoma, and Texas each used more than 95 MGD of surface water for livestock and accounted for 37 percent of surface-water withdrawals for this use.

Figure 3.1-12. Total surface water and groundwater withdrawals, 2005 (USGS, 2009)

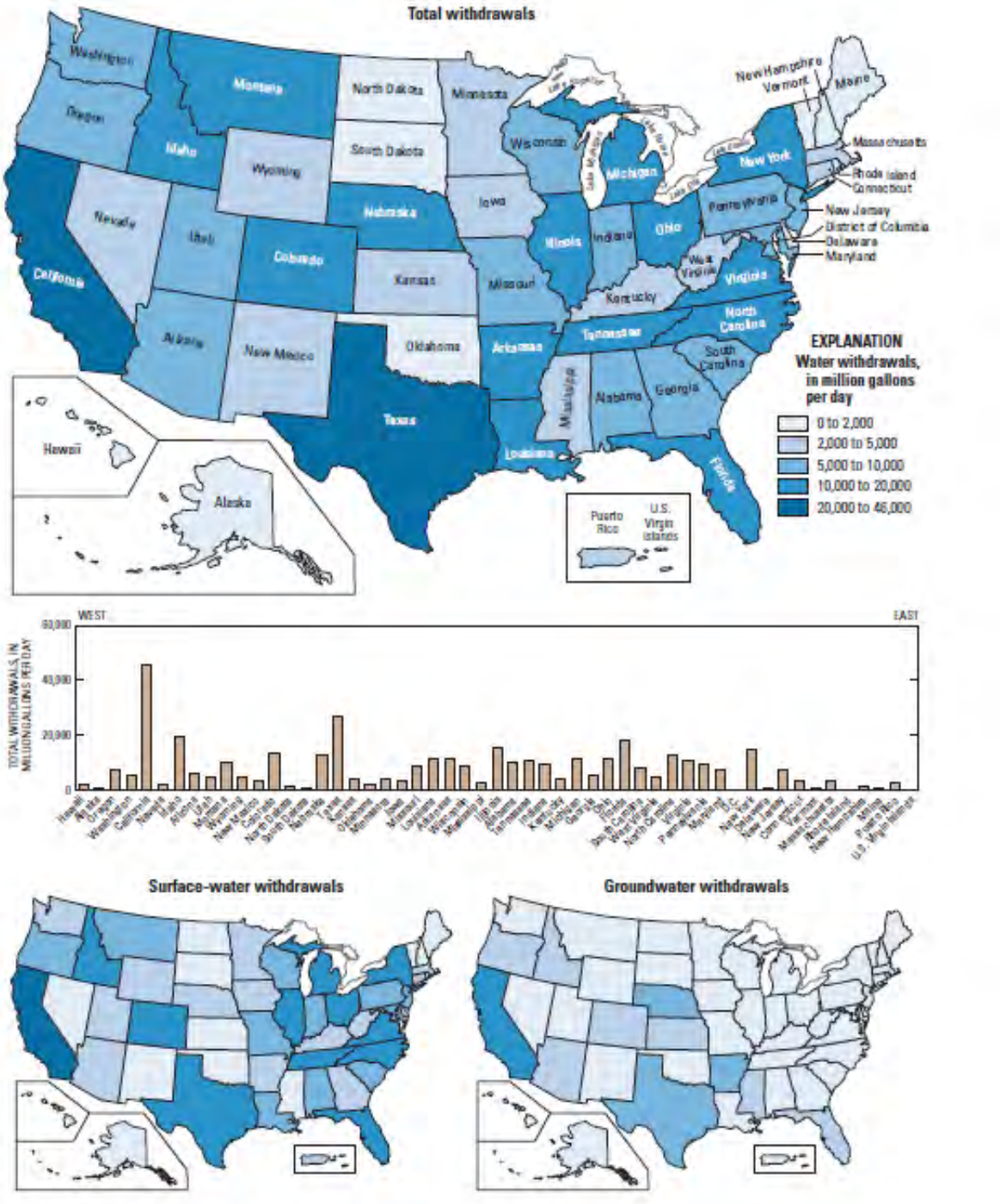


Figure 3.1-13. Irrigation water supply and withdrawals by source and state, 2005 (USGS, 2009)

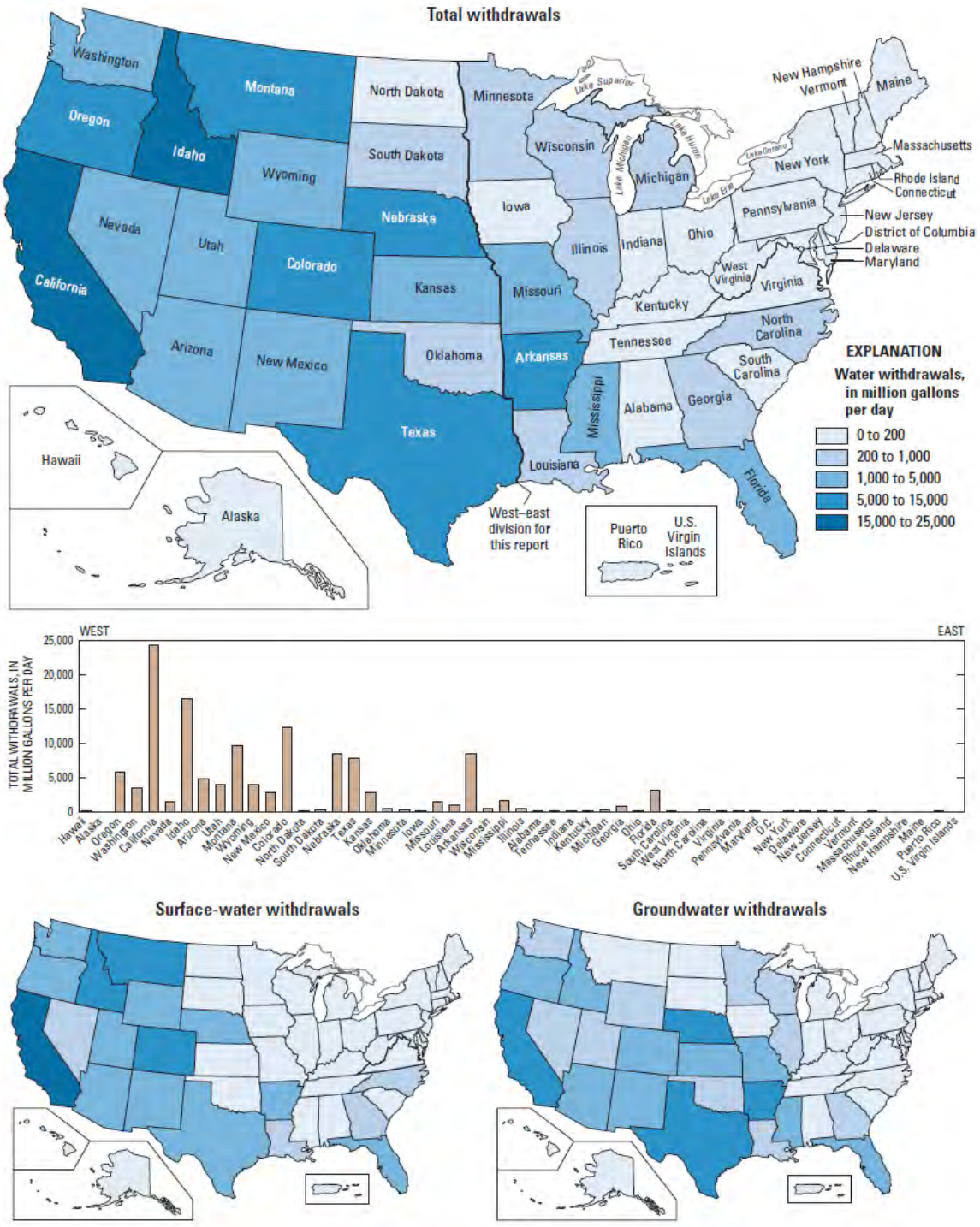
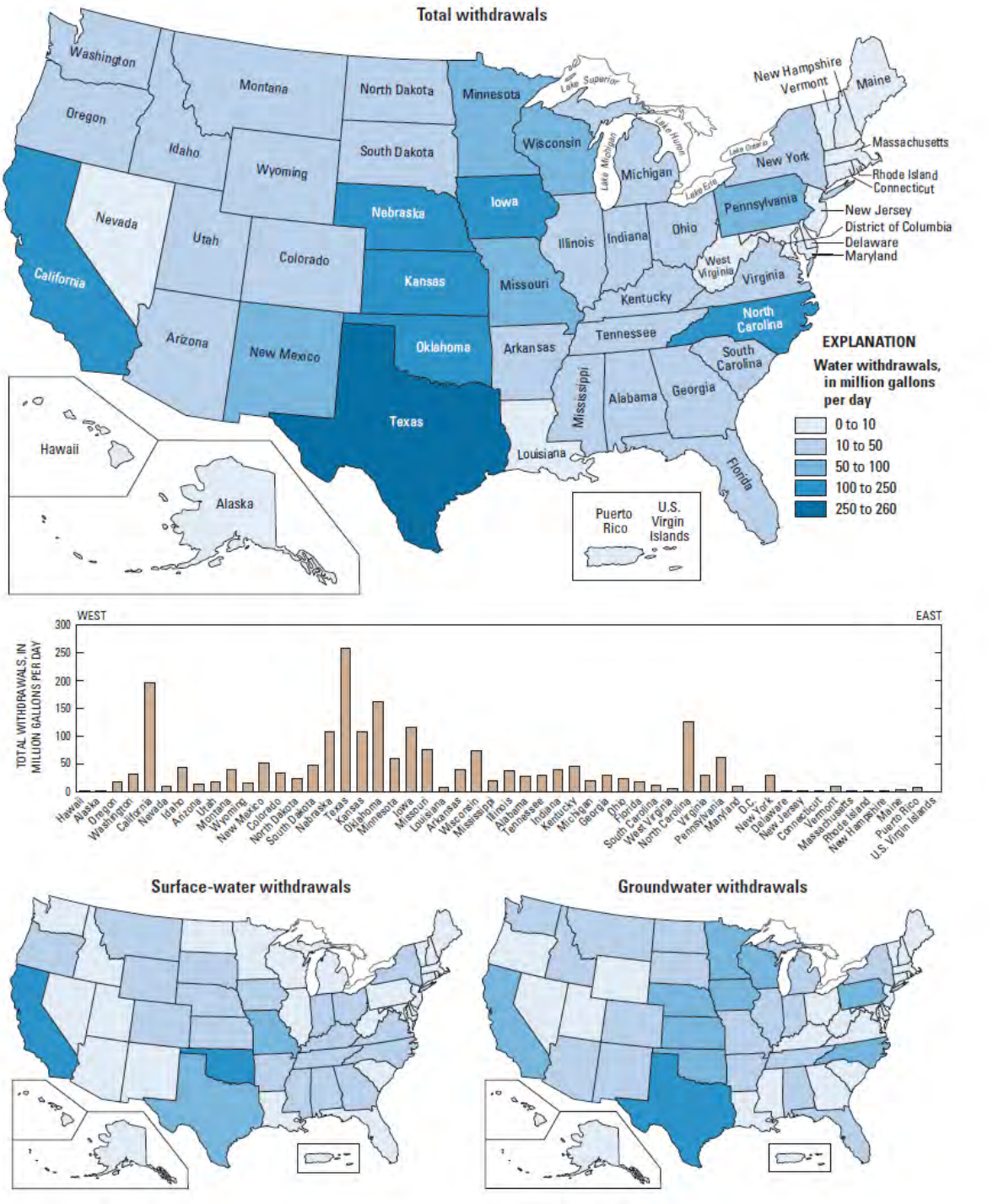


Figure 3.1-14. Livestock water withdrawals by source and state, 2005 (USGS, 2009)



3.1.3.9 Data Sources Used to Establish the Background Environmental Conditions

Surface Water Quality

NAWQA provides an understanding of whether water quality is getting better or worse over time; and how natural features and human activities affect those conditions (USGS, 2010). As discussed by USGS (2010), regional and national assessments are possible because of a consistent study design and uniform methods of data collection and analysis. Monitoring data are integrated with geographic information on hydrological characteristics, land use, and other landscape features in models to extend water-quality understanding to unmonitored areas. Local, state, tribal, and national stakeholders use NAWQA information to design and implement strategies for managing, protecting, and monitoring water resources.

CWA Geospatial data from EPA's Office of Water Programs, including 303(d) Impaired Waters, 305(b) Assessed Waters and TMDLs are available for download by watershed, state, or to a national extent. Generally, state-level geospatial data represents the most recent data submitted to EPA by states. Table 3.1-1 presents the number of impaired waters listed by state. According to the EPA tabulated data, pathogens are the leading cause of impairment for 303(d) listed waters (Table 3.1-2). The specific reported causes of impairment that make up the selected impairment group and the number of each cause of impairment reported are listed in Table 3.1-3.

Table 3.1-1. Impaired waters listed by state, 2010 (EPA, 2014g)

State	Miles	State	Miles	State	Miles	State	Miles
Alabama	283	Indiana	1,836	New Hampshire	1,449	Tennessee	1,028
Alaska	35	Iowa	480	New Jersey	716	Texas	719
Arizona	91	Kansas	1,372	New Mexico	209	Utah	156
Arkansas	225	Louisiana	236	New York	1,543	Vermont	104
California	1,021	Maine	114	North Carolina	1,130	Virginia	1,523
Colorado	244	Maryland	184	North Dakota	201	Washington	2,420
Connecticut	461	Massachusetts	720	Ohio	267	West Virginia	1,097
Delaware	101	Michigan	2,352	Oklahoma	657	Wisconsin	593
District of Columbia	36	Minnesota	1,144	Oregon	1,397	Wyoming	107
Florida	2,292	Mississippi	229	Pennsylvania	6,957		
Georgia	215	Missouri	257	Puerto Rico	213		
Hawaii	309	Montana	584	Rhode Island	120		
Idaho	741	Nebraska	342	South Carolina	961		
Illinois	1,057	Nevada	215	South Dakota	155		

Table 3.1-2. Causes of water quality impairment and the number of cases for each cause for 303(d) listed waters, 2010 (EPA, 2014g)

Cause	No.	Cause	No.	Cause	No.	Cause	No.
Pathogens	10,783	Temperature	3,134	Other Cause	475	Biotoxins	87
Nutrients	7,686	Turbidity	2,899	Toxic Organics	457	Trash	84
Metals (other than Mercury)	7,229	Pesticides	2,096	Ammonia	408	Noxious Aquatic Plants	83
Organic Enrichment/ Oxygen Depletion	6,720	Salinity/Total Dissolved Solids /Chlorides/ Sulfates	1,931	Toxic Inorganics	378	Cause Unknown - Fish Kills	68
Sediment	6,565	Algal Growth	1,265	Flow Alteration(s)	238	Radiation	52
Polychlorinated Biphenyls (PCBs)	5,806	Cause Unknown	1,147	Oil and Grease	192	Chlorine	52
Mercury	4,802	Habitat Alterations	811	Taste, Color and Odor	142	Nuisance Native Species	4
pH/Acidity/Caustic Conditions	4,341	Dioxins	621	Nuisance Exotic Species	119		
Cause Unknown - Impaired Biota	3,664	Total Toxics	514	Fish Consumption Advisory	101		

Total: 74,954 Cases of Impairment

Table 3.1-3. Specific causes of impairment that make up the national pathogens cause of impairment group, 2010 (EPA, 2014g)

Cause of impairment	Number of cases	Cause of impairment	Number of cases
Fecal coliform	4,452	Indicator bacteria	312
E. coli	3,446	Total coliform	80
Pathogens	814	Coliforms	37
Enterococcus bacteria	589	Bacteria (Oyster waters)	16
Bacteria	464	Bacterial slimes	2
		Sanitary waste	1

The causes for impaired surface water within the states that contain regions B, C, D, L, and U, are summarized in Tables 3.1-4 through 3.1-7. In all of these states pathogens are reported as one of the top three causes of impairment. In addition, the TMDL summary pathogen data tabulated by the EPA (Table 3.1-8) indicates that large numbers of stream and river miles are impaired.

Table 3.1-4. California causes of impairment for 303(d) listed waters, 2010 (EPA, 2014g)

Cause of impairment	Cases	Cause of impairment	Cases	Cause of impairment	Cases
Pathogens	526	Sediment	71	Algal Growth	18
Pesticides	437	Temperature	59	Taste, Color and Odor	13
Metals (other than Mercury)	293	Trash	46	Other Cause	10
Total Toxics	239	Turbidity	46	Flow Alteration(s)	6
Salinity/Total Dissolved Solids/Chlorides/Sulfates	183	Ammonia	42	Biotoxins	6
Nutrients	179	Toxic Organics	40	Habitat Alterations	5
Mercury	160	Toxic Inorganics	37	Oil and Grease	2
Organic Enrichment/Oxygen Depletion	116	Nuisance Exotic Species	30	Fish Consumption Advisory	2
Polychlorinated Biphenyls	116	Dioxins	28	Cause Unknown - Fish Kills	1
pH/Acidity/Caustic Conditions	108	Cause Unknown - Impaired Biota	21		

Total: 2,840 cases of impairment

Table 3.1-5. Washington causes of impairment for 303(d) listed waters, 2010 (EPA, 2014g)

Cause of impairment	Cases	Cause of impairment	Cases	Cause of impairment	Cases
Temperature	988	Toxic Organics	135	Total Toxics	26
Pathogens	954	Metals (other than Mercury)	68	Turbidity	19
Organic Enrichment/ Oxygen Depletion	731	Dioxins	62	Ammonia	14
pH/Acidity/Caustic Conditions	294	Nutrients	50	Cause Unknown - Impaired Biota	13
Pesticides	228	Other Cause	43	Sediment	9
Polychlorinated Biphenyls	146	Mercury	30	Chlorine	3

Total: 3,813 cases of impairment

Table 3.1-6. Florida causes of impairment for 303(d) listed waters. 2010 (EPA, 2014g)

Cause of impairment	Cases	Cause of impairment	Cases	Cause of impairment	Cases
Mercury	1,128	Metals (other than Mercury)	114	Other Cause	17
Organic Enrichment/ Oxygen Depletion	1,049	Cause Unknown - Impaired Biota	37	pH/Acidity/Caustic Conditions	12
Pathogens	608	Turbidity	25	Noxious Aquatic Plants	1
Algal Growth	350	Salinity/Total Dissolved Solids/Chlorides/Sulfates	21	Dioxins	1
Nutrients	263	Ammonia	19	Chlorine	1

Total: 3,646 cases of impairment

Table 3.1-7. Arizona causes of impairment for 303(d) listed waters, 2010 (EPA, 2014g)

Cause of impairment	Cases	Cause of impairment	Cases	Cause of impairment	Cases
Metals (other than Mercury)	37	Ammonia	9	pH/Acidity/Caustic Conditions	5
Pesticides	30	Sediment	8	Toxic Inorganics	3
Pathogens	21	Nutrients	8	Chlorine	2
Mercury	12	Organic Enrichment/ Oxygen Depletion	6	Nuisance Native Species	1

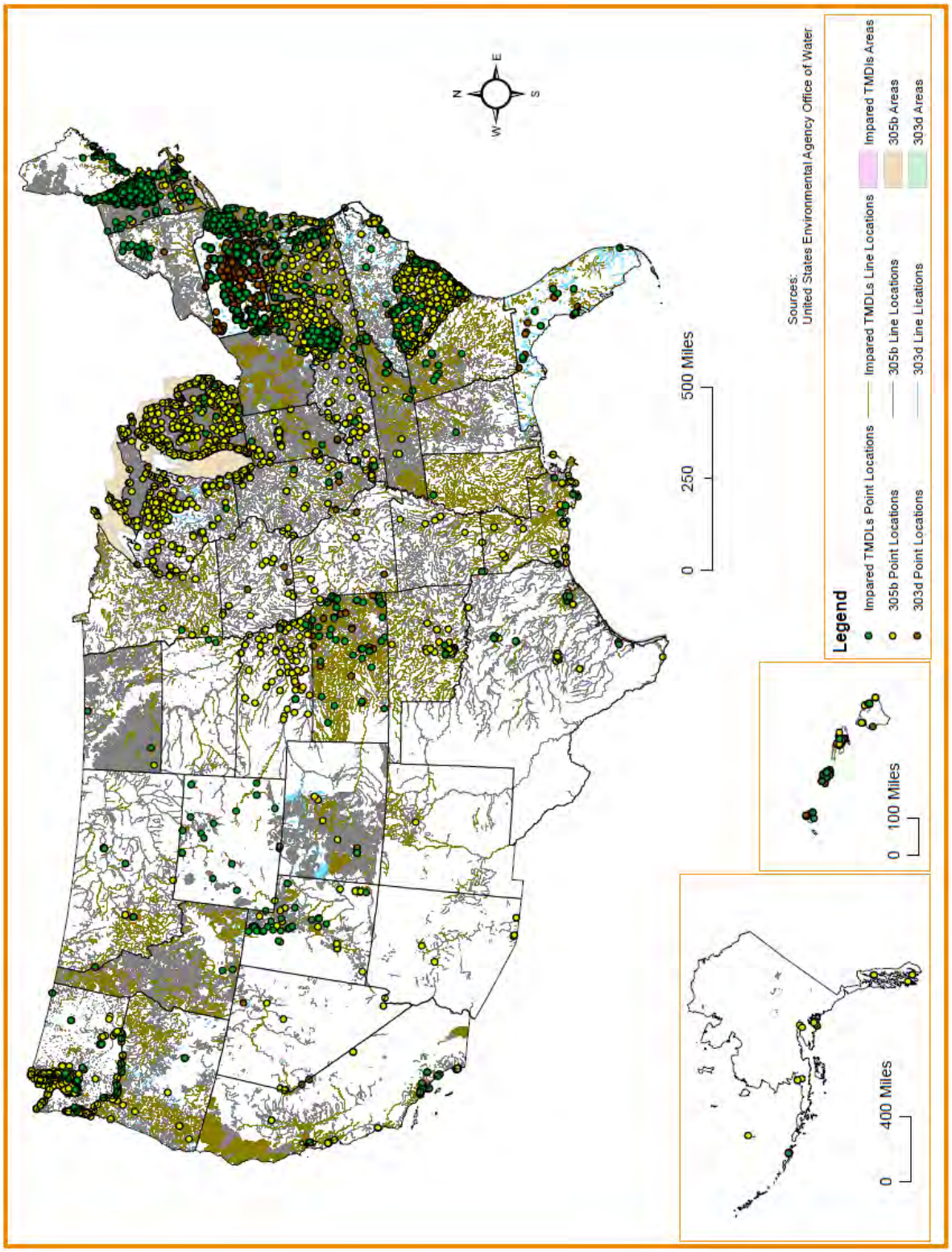
Total: 142 cases of impairment

Table 3.1-8. Nationwide miles of impaired streams (EPA, 2014h)

Cause of Impairment	Rivers and Streams (Miles) Impaired
Bacteria	7,394 mi.
Bacterial slimes	30 mi.
Coliform bacteria	269 mi.
Enterococcus bacteria	10,152 mi.
E. coli bacteria	86,747 mi.
Fecal bacteria	108 mi.
Fecal coliform bacteria	57,562 mi.
Indicator bacteria (only)	942 mi.
Pathogens	4,184 mi.
Total coliform	6,705 mi.
Viruses	6 mi.

Nitrates are often observed in surface and groundwater in agricultural areas. Reported TMDL exceedances are shown in Figure 3.1-15.

Figure 3.1-15. 303(d) Impaired waters due to nitrate exceedances



Groundwater Quality

As described in USGS (2006b), fecal and sewage contamination of water can introduce pathogenic microorganisms into a water resource. Data obtained from the collection of water samples from wells and analyzed for the presence of fecal-indicator microorganisms can be used in multiple ways. Perhaps most importantly, data indicating the presence or absence of fecal-indicator microorganisms in groundwater samples can help determine the suitability of a water resource for different purposes, particularly as a drinking-water or irrigation resource (USGS, 2006b).

As part of NAWQA, USGS collected microbiological data from wells in 22 NAWQA study units during 1993–2004 (Figure 3.1-16) (USGS, 2006b). The wells constituted the sampling networks for three major NAWQA efforts—the major aquifer study, the land-use study, and source-water quality assessments of groundwater used for public supplies. Sixteen principal aquifers were represented by these well networks (Figure 3.1-17). Samples of untreated groundwater were analyzed for concentrations of fecal-indicator bacteria, which included the total-coliform bacteria, fecal-coliform bacteria, and *E. coli,* and for the presence of somatic and male-specific coliphage viruses.

Analyses of the samples showed that coliform bacteria occur relatively frequently—nearly 30 percent of all wells tested positive—and that domestic wells commonly are contaminated by total coliform bacteria, with 33 percent of these wells testing positive (Figure 3.1-18). Coliphage viruses were present in 10 percent or fewer of the wells sampled in the Central Columbia Plateau-Yakima, Georgia-Florida, San Joaquin, and Trinity study units, which represent the Columbia Plateau, Floridan, Central Valley, and Coastal Lowlands principal aquifers, respectively. The frequency of detections and concentrations of total coliform bacteria generally were higher in samples from domestic wells than in samples from public-supply wells; in fractured or porous rock materials (carbonate rocks) than in unconsolidated materials (mixtures of sand, gravel, clay); and in principal aquifers with median depths of sampled wells ranging from 100 to 200 feet than in principal aquifers with median depths of sampled wells less than 100 feet or greater than 200 feet.

The waters most affected by the presence of coliform bacteria were those in the Valley and Ridge, the Floridan, and the Piedmont and Blue Ridge aquifers, where more than 50 percent of the study wells tested positive for these bacteria. The numbers of wells with detections of coliform bacteria were significantly lower for the Glacial Deposits, Stream and River Valley, Columbia Plateau, Basin and Range, High Plains, Southeastern Coastal Plain, and Coastal Lowlands aquifers. Of the 16 principal aquifers sampled, wells in the Valley and Ridge had the highest overall concentrations of total coliforms, with a median of 2 CFU/100 ml. Elevated concentrations of coliform bacteria (greater than 300 CFU/100 ml) also were reported for wells completed in the Mississippian-Pennsylvanian aquifer and the Ordovician aquifer in lower Tennessee.

For the large Major Aquifer Study (MAS) network, the frequency of wells testing positive for total coliform was 82 percent for the Central Valley aquifer (Figure 3.1-18A); however, this high

frequency of detection might be a function of the low number of available samples. Detection - frequencies of *E. coli* were highest for MAS wells in the Ordovician aquifer (30 percent), followed by detections in the Central Valley (25 percent) and the Mississippian-Pennsylvanian (19 percent) aquifers (Figure 3.1-18A).

The Piedmont and Blue Ridge, Floridan, Coastal Lowlands, Columbia Plateau, Glacial Deposits, Basin and Range, and Central Valley aquifers, or just less than one-half the 16 aquifers studied since 1993, were the first principal aquifers to be sampled as part of the new Source-Water Quality Assessment (SWQA) network of NAWQA Cycle II. Samples with the highest detection frequencies of total coliforms were collected from Piedmont and Blue Ridge wells (greater than 50 percent) followed by detections in samples from wells completed in the Floridan aquifer (30 percent). Detection frequencies of *E. coli* were low, however, with nondetections reported for all wells in four of the seven aquifers and only one detection in each of the others (Figure 3.1-18B).

Total coliforms were detected in 33 percent of the samples from domestic wells and 16 percent of samples from public supply wells, and *E. coli* were detected in eight and three percent of samples from domestic and public supply wells, respectively (Figure 3.1-19A).

Median concentrations of total coliforms and *E. coli* were at the detection limit of less than one CFU/100 ml for all six classes of water use (Figure 3.1-19B); however, the concentrations in domestic wells were significantly higher (p-value less than 0.05) than concentrations in public-supply wells. In samples from domestic wells, the maximum concentrations of total coliforms and *E. coli* were 1,600 and 1,200 CFU/100 ml, respectively. Maximum concentrations of total coliforms detected in samples from public-supply wells were greater than 80 CFU/100 ml for a well completed in the Floridan aquifer of the Georgia/Florida (GAFL) study unit, and 61 CFU/100 ml for a well completed in the Glacial Deposits aquifer of the High Plains Region Groundwater (HPGW) study unit. More than 75 percent of samples from domestic wells had concentrations of total coliforms of 2 CFU/100 ml or less. In samples from public-supply wells, however, more than 75 percent of concentrations of total coliforms were less than the minimum report level of less than one CFU/100 ml (Figure 3.1-19B).

Figure 3.1-16. Study units of the NAWQA program in which microbiological samples were collected from wells, 1993–2004 (USGS, 2006b).

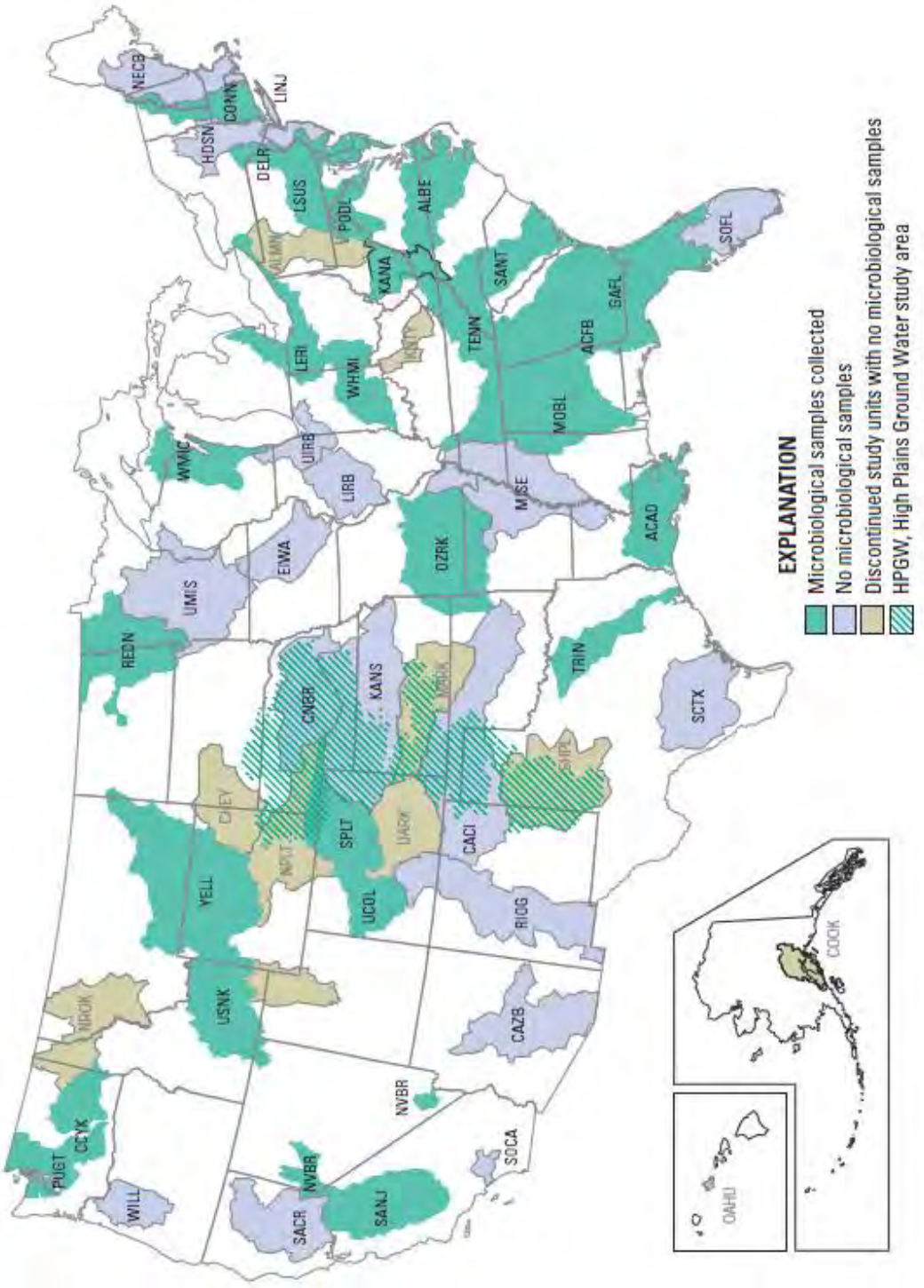


Figure 3.1-17. Locations of wells in principal aquifers that tested positive for fecal-indicator bacteria (A) and wells where fecal-indicator bacteria were not detected in samples collected for the NAWQA program (B), 1993–2004 (USGS, 2006b).

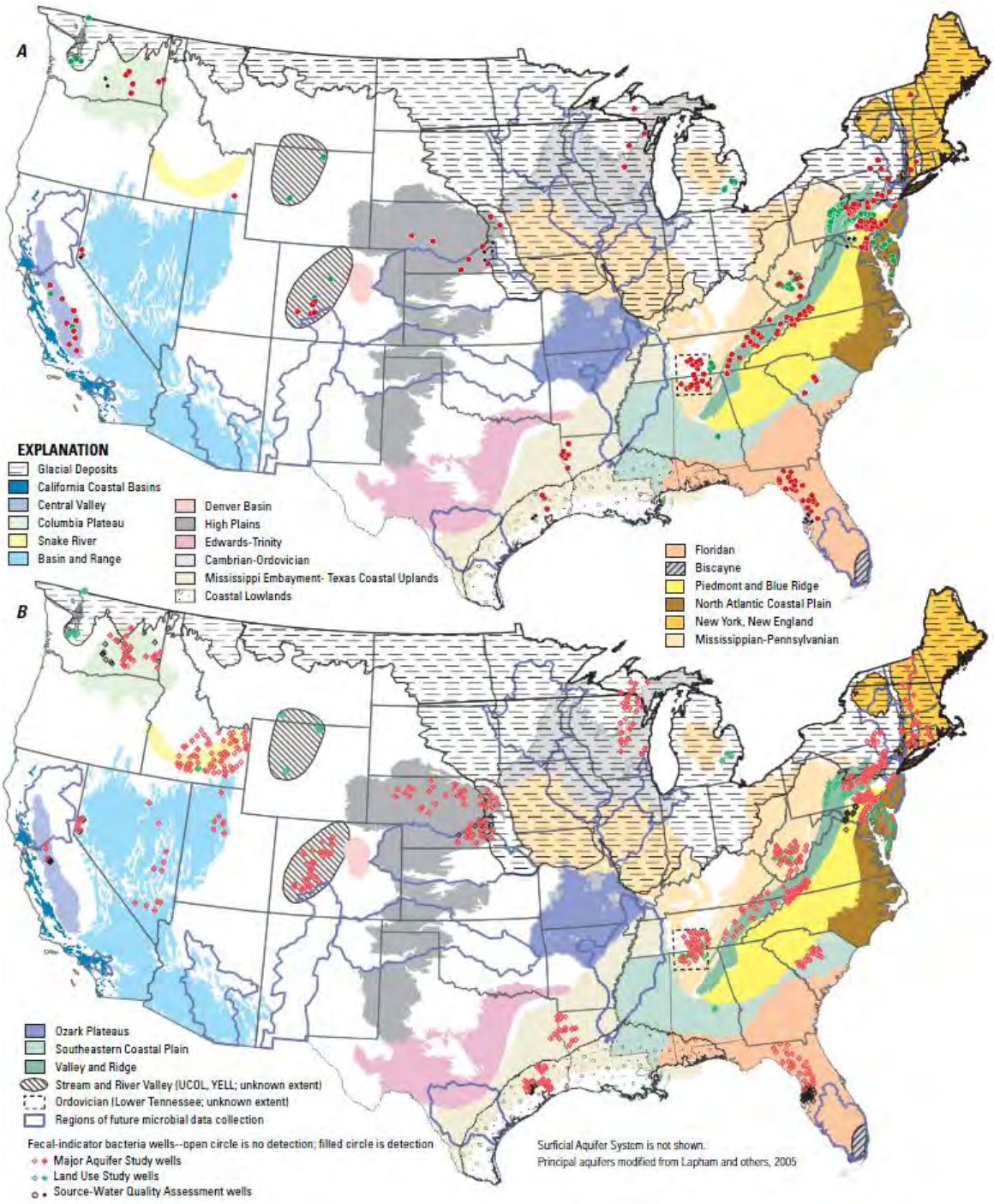


Figure 3.1-18. Percentage of wells testing positive for coliform bacteria (A), and concentrations of coliform bacteria by class of water use (B) in samples collected in MAS and SWQA wells in 22 study units (USGS, 2006b)

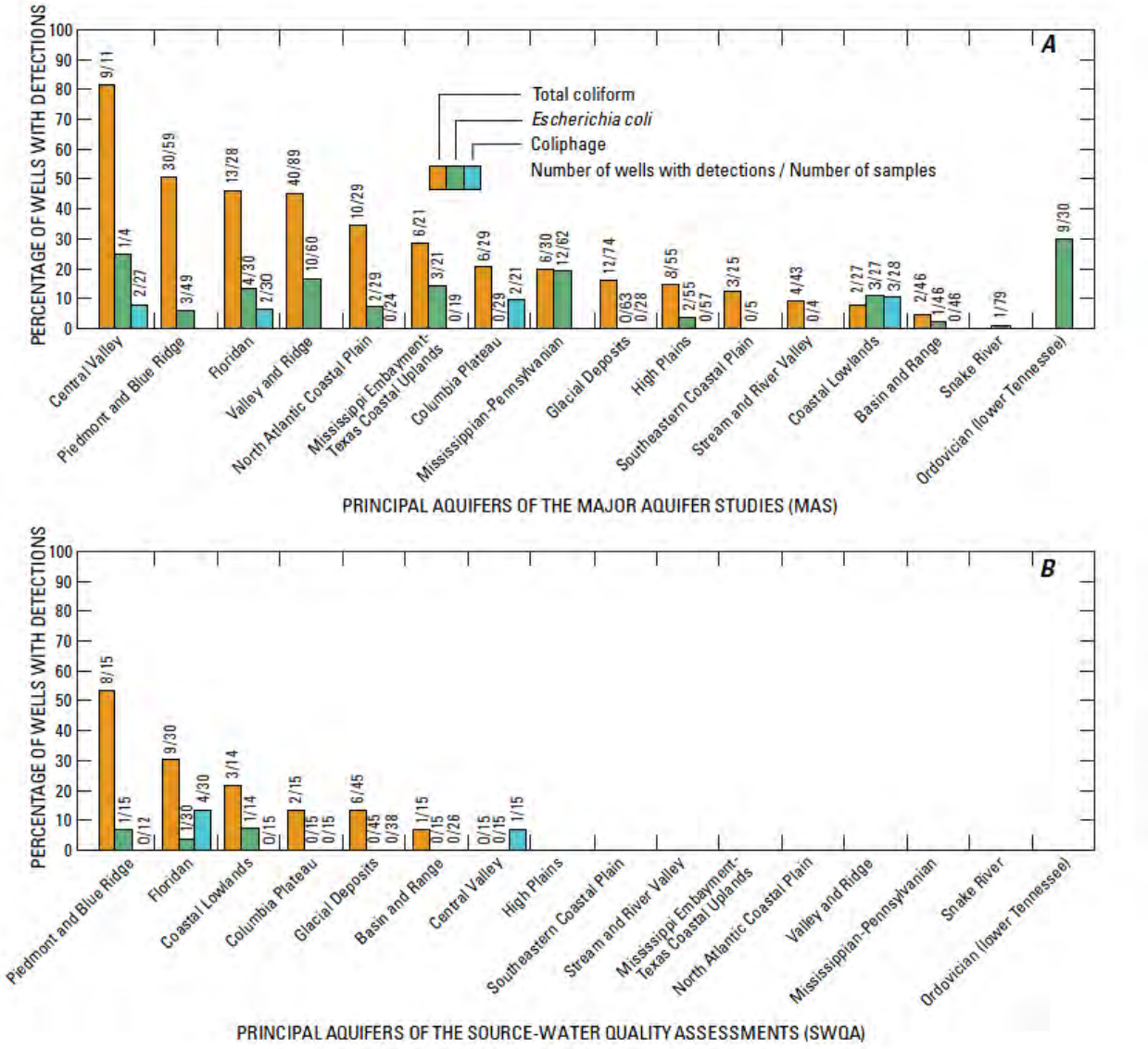
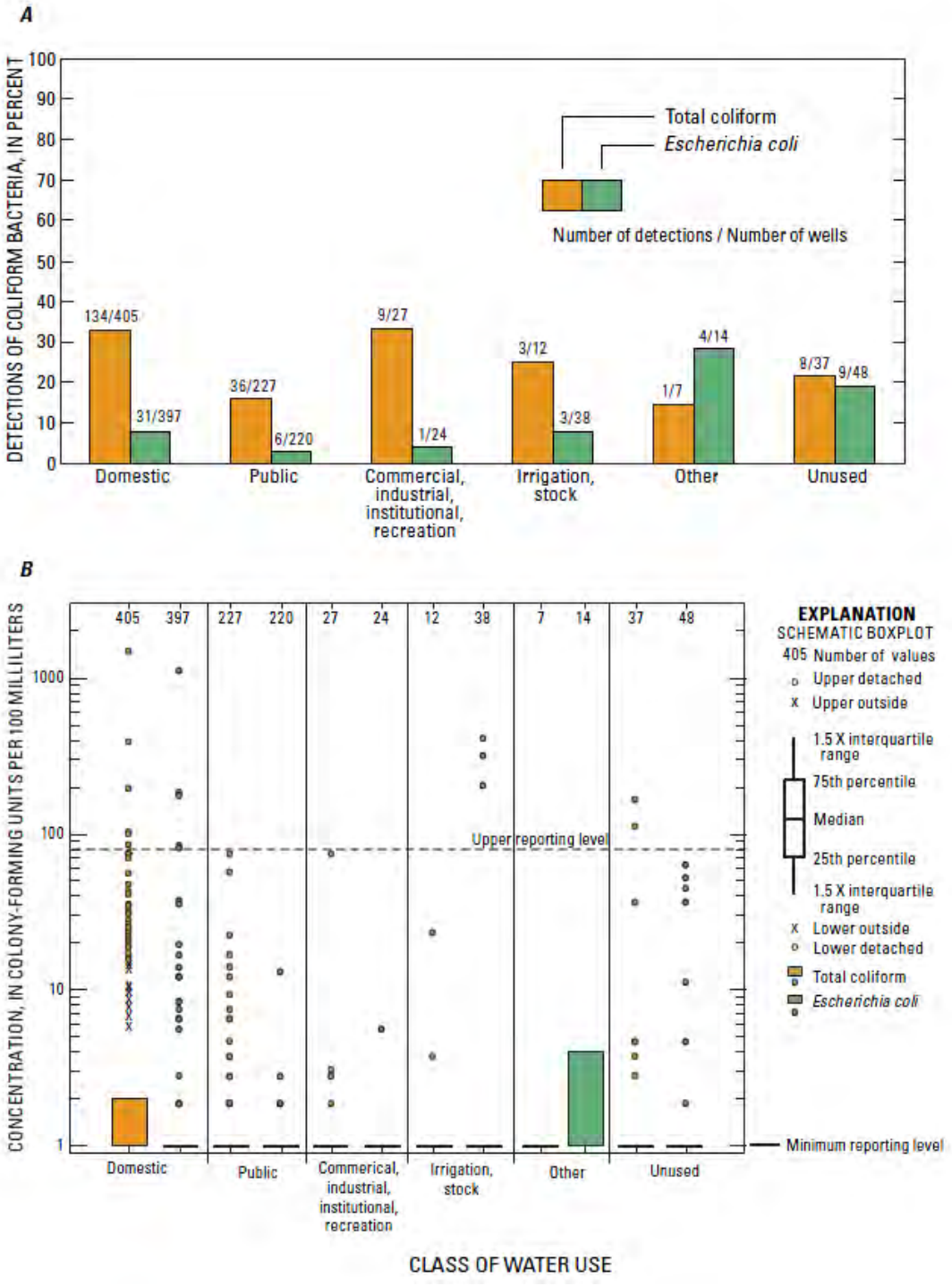


Figure 3.1-19. Percentage of detections of coliform bacteria and coliphage virus in wells sampled as part of the MAS (A) and SWQA (B) for the NAWQA program, 1993–2004 (USGS, 2006b).



3.1.3.10 Sources of Contamination Derived from Treatment of Irrigation Water

Treatment technologies to remove pathogens from irrigation water range from the conventional physical (heat pasteurization and filtration) and chemical (biocides) methods to the more advanced technologies of radiological (UV light) and ozone treatment. Each type of technology has benefits and limitations depending on the method of irrigation. For example, it would not be practicable to filter the large volumes of water associated with most crops grown under surface irrigation practices. They also have the flexibility to be used alone or in conjunction with each other to improve removal efficiencies (e.g., filtration followed by UV light treatment). A primary issue of concern regarding treatment of irrigation water with chemicals is the potential residual effect of the chemicals on beneficial microbial species (referred to as residual disinfection).

Heat Pasteurization is a method by which pathogens are destroyed by elevating the temperature of the water to 203° F for 30 seconds or more. While this method requires input of energy to heat the water, there are no residual disinfection concerns with respect to beneficial microbial species in the soil column.

Filtration is the physical removal of pathogens from the water. Filtration typically begins with a settlement process followed by forcing water through a semi-permeable membrane (or series of membranes) or micron filter media to trap all particulates above a certain size, including pathogens. Filtration requires pumps to force the water through the membranes or micron media filters and is limited by the rate at which large volumes of water can be processed. Passive flow of water through sand or other filter media is also a filtration method, less energy intensive than pumps and membranes. Maintenance required on filtering systems includes period replacement of filter media, pump maintenance and power supply. There are no residual disinfection concerns with respect to beneficial microbial species in the soil column.

Ozone (i.e., triatomic oxygen or O_3) treatment has been effectively used as a disinfectant for drinking water in Europe for the past 100 years (EPA, 1999a). Ozone is a strong oxidizer but does not remain as a component of the treated water due to its rapid decomposition; therefore, there are no concerns regarding residual disinfection of beneficial soil microbes. One drawback of ozonation is the potential oxidization of iron and manganese contained in the irrigation water causing precipitation of hydroxides formed by these elements (e.g., ferric hydroxide and manganese hydroxide). Precipitation of these compounds could result in crop deficiencies of both iron and magnesium.

Ultraviolet light treatment is being effectively utilized for sterilization of irrigation water. Limitations of UV light treatment include the clarity of the water being treated. The more suspended solids in the water column, the less effective the treatment will be. There are no known residual disinfection concerns with UV light treatment.

The use of chemicals, or biocides, is an accepted method of controlling pathogens in agricultural irrigation water. The efficacy of this treatment is dependent on the concentration of pathogens in the source water as well as the concentration of biocides. Residual disinfection of beneficial microbial species in the soil column is a potential concern associated with use of biocides to treat agricultural irrigation water.

The most common chlorine chemicals that are used in agriculture to disinfect bacteria and viruses are sodium hypochlorite, calcium hypochlorite, gaseous chlorine and chlorine dioxide. Trihalomethanes (THMs) are commonly formed when the naturally occurring organics in water react with reactive chlorine producing species such as free chlorine (Cl_2), sodium hypochlorite (NaOCl), or hypochlorous acid (HClO) (Jackman and Hughes, 2009). Under most conditions (except in the presence of unusually high bromide concentrations), chloroform is the THM produced in the highest concentrations during chlorination. THMs, which include chloroform, bromodichloromethane, dibromochloromethane, and bromoform are carcinogenic and are designated by EPA as priority pollutants. Furthermore, in most cases where more than one THM is produced from chlorination, the relative concentrations among the different compounds usually decrease with increasing bromination (chloroform > dichlorobromomethane ≥ chlorodibromomethane ≥ bromoform) (USGS, 2004).

Chloroform is one of the volatile organic compounds (VOCs) detected most frequently in both ground and surface water (Ivahnenko and Barbash, 2004). Because chloroform is a suspected human carcinogen, its presence in drinking water is a potential human health concern. Liver damage, however, is known to occur at chloroform exposures lower than those required to cause cancer; an observation that has been considered by the EPA as the basis for setting the maximum contaminant level of 80 µg/L for total THMs. Chloroform has been widely detected in national, regional, and local studies of VOCs in ground, surface, source, and drinking waters.

Although much is known about disinfection processes and factors that influence by-product formation, less is known about their fate in the environment. Most groundwater recharge is done with chlorination-disinfected wastewaters. Studies have shown that in surface waters THMs volatilize (USGS, 2002).

The EPA's Toxic Release Inventory (TRI) documents industrial releases of a broad range of anthropogenic compounds to the environment on a nationwide basis. In the U.S., these releases are reported annually and include discharges to surface water, and releases to land. According to the TRI, a total of approximately 1.6 million pounds of chloroform was released by these routes across the Nation in 2001 (USGS, 2004).

Discharges and releases of chloroform to surface water and land, as reported by the TRI, decreased from 1988 to 2001 (Figure 3.1-20 and Figure 3.1-21, respectively). Releases to land, as defined by the EPA, include disposal or burial of chemicals in landfills, application farming (in which the chemical is incorporated into the soil, a practice also known as land treatment), spills, leaks, and leaching from surface impoundments and waste piles (EPA, 1999b).

Releases of chloroform through industrial practices to surface water and land represent approximately 1.2 and 0.5 percent, respectively, of the total releases of anthropogenic chloroform to the environment. As noted earlier, most of the chloroform released to the hydrologic system by human activities is through air emissions.

Figure 3.1-20. Industrial discharges of chloroform to surface water in the U.S. from 1988 through 2001 (USGS, 2004)

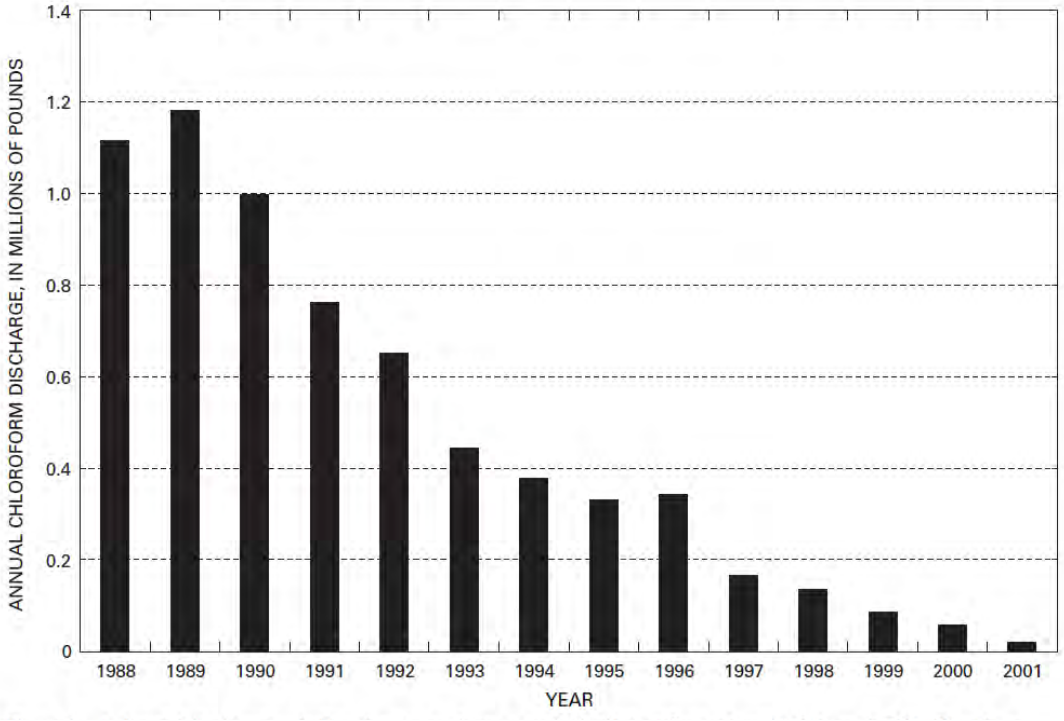
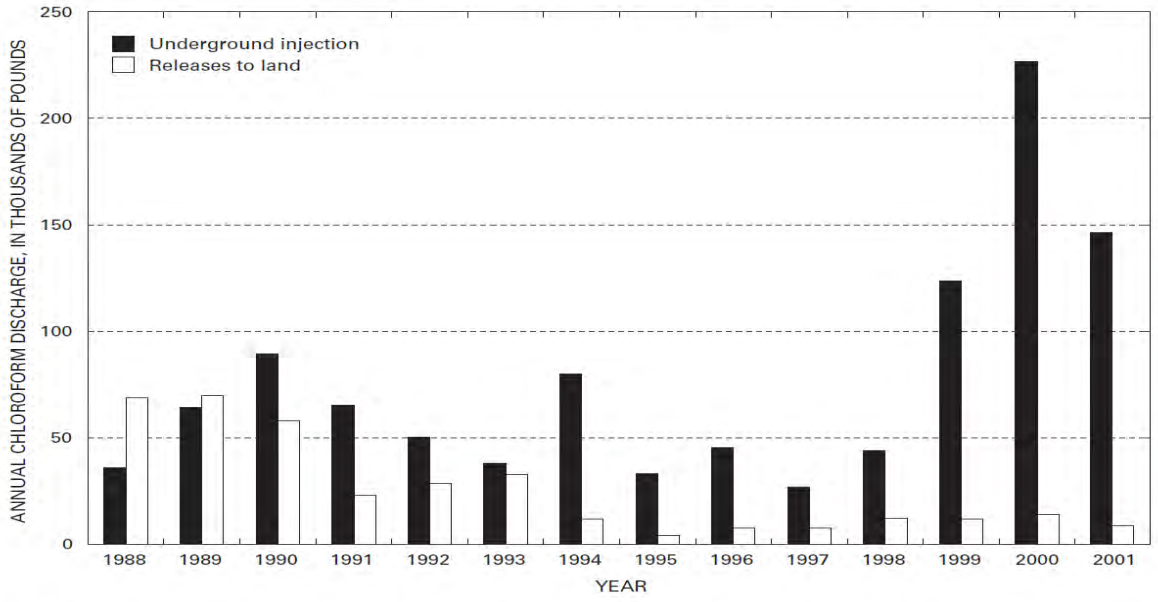


Figure 3.1-21. Industrial discharges of chloroform by underground injection and releases to land in the U.S. from 1988 through 2001 (USGS, 2004)



A national water quality assessment performed by the USGS was designed to provide additional information on the frequency of occurrence, concentration, and temporal variability of THMs in source water used by community water systems (CWSs) (USGS, 2003b). This study found that THMs were detected in 47.8 percent of the CWSs supplied by surface water. Total THM concentrations of the compound, however, were typically less than the Maximum Concentration Limit (MCL).

In the studies that compared land-use settings, frequencies of detection of chloroform were higher beneath urban and residential areas than beneath agricultural or undeveloped areas (Ivahnenko and Barbash, 2004).

The frequent occurrence of THMs in reservoir source waters was determined to be an artifact of disinfection and the recycling of chlorinated water to these reservoirs. All CWSs with frequent occurrence of THMs served by a reservoir indicated that chlorine was added to waters for various reasons and that the chlorinated water was then released back to, or upstream of, the reservoir or lake that was sampled.

Based on its high volatility, chloroform is expected to be present mostly in the vapor phase following its release to the atmosphere. However, because the compound also is relatively water soluble, some removal of atmospheric chloroform is expected to occur during rainfall events, as demonstrated by the fact that it has been detected in precipitation (USGS, 2004). Since chloroform is relatively volatile it is expected that much of the chloroform in surface waters is likely to volatilize soon after its release.

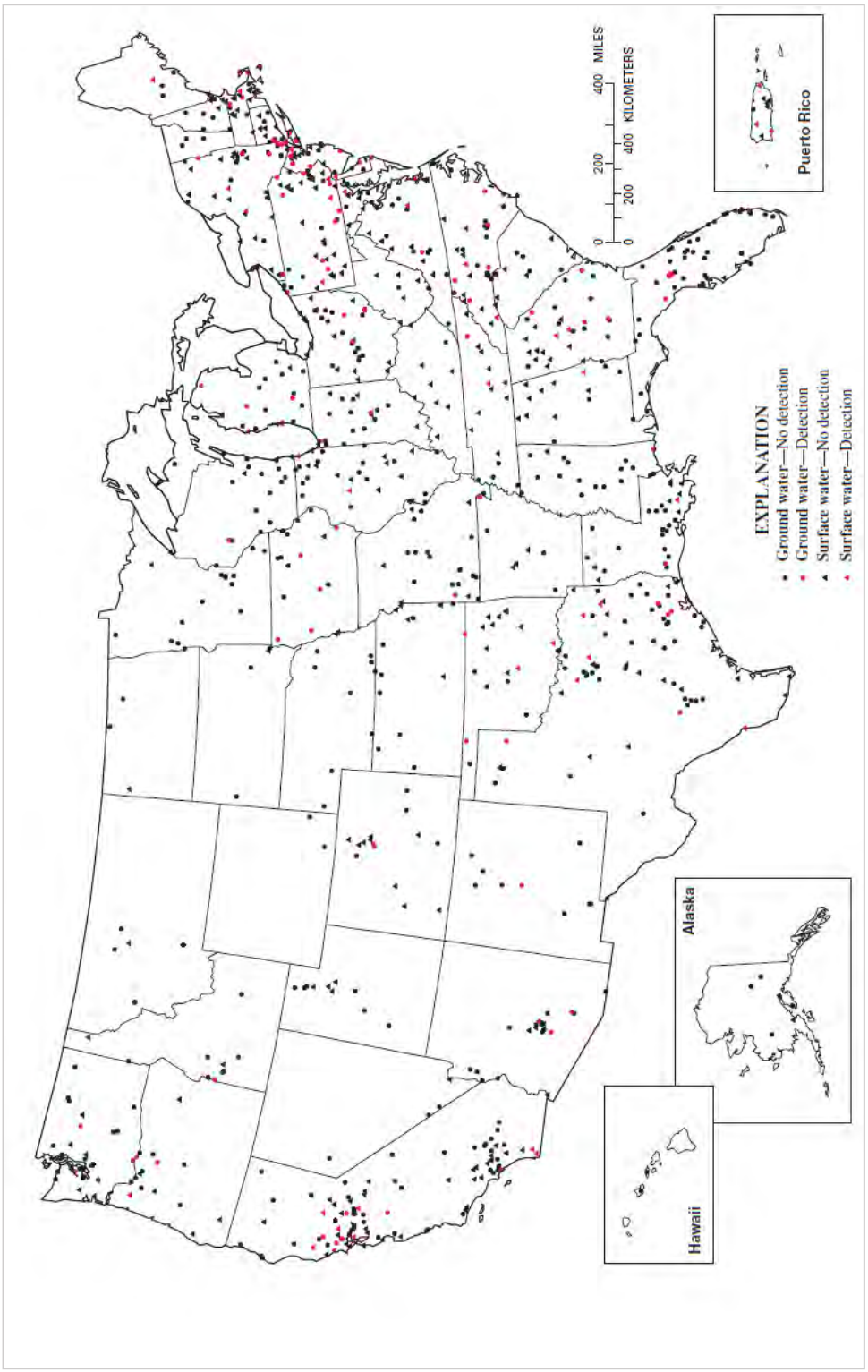
As might be anticipated from fundamental principles of mass transfer (USGS, 2004), the rate of chloroform volatilization from streams increases with increasing water velocity, as well as with decreasing stream depth. Also in accord with theory is the observation noted previously that chloroform volatilization rates, like the Henry's Law constant, increase with increasing temperature (USGS, 2004).

Figure 3-1.22 summarizes data on chloroform detections in untreated groundwater from a variety of studies ranging in scale from individual urban areas to the entire U.S. (USGS, 2004). For all of the studies listed, chloroform was the VOC detected most frequently in groundwater. However, with the exception of the investigation by Squillace et al. in 1999, all of the sampled groundwater contained Total THM (TTHM) concentrations that were less than the EPA MCL of 80 µg/L for TTHMs (USGS, 2004). Figure 3.1-22 presents data on THM detections in ground and surface water from the national study conducted by S. J. Grady in 2003 (USGS, 2004).

The Oregon State University Extension Service prepared a publication titled *Understanding pesticide persistence and mobility for groundwater and surface water protection* (Kerle, Jenkins, and Vogue, 2007). This publication, which is based upon University research and observations, details the factors that contribute to pesticide transport, persistence, and fate resulting from agricultural applications. Soil properties (soil being the medium where pesticides are most often applied) such as pH, microbial activity (presence of fungi and bacteria may break down components of pesticides), moisture, texture, organic matter, and temperature may all play important roles in the degradation and persistence of pesticides. For example, in soils where

there is high organic matter, pesticides may be broken down more readily than in soils where there is low moisture and organic content. Drier soils, which are more erodible, may result in less opportunity for degradation of pesticides and also in an increased rate of transport with runoff, or the pesticide compounds may sorb with soils and be transported with wind erosion. Pesticides that remain on soil surfaces may volatilize and become airborne, or dissolve in water and move with wind or eroded soils in the water medium. Pesticides that are exposed to sunlight may undergo photodegradation. The authors also noted that such compounds may degrade from exposure to other chemicals within soils or water. Runoff from rain events is a chief mode of transport for pesticide compounds. The pesticide may dissolve in water and become an important point of exposure to vegetation and wildlife. Pesticide persistence is generally measured in values of "half-life." The half-life of most pesticides is measured in days. It is noteworthy that persistence in the environment may vary depending upon the chemical make-up of the pesticide and environmental factors (e.g., moisture, soils properties, temperature, sunlight, etc.) (Kerle, Jenkins, and Vogue, 2007).

Figure 3.1-22. Detections of total trihalomethanes at or greater than 0.2 micrograms per liter in ground and surface waters sampled for the American Water Works Research Foundation national study (USGS, 2004)



3.1.3.11 Groundwater Depletion

A shift from surface water resources to pumping groundwater has been shown to stress aquifer(s) and increase groundwater depletion. The USGS has completed a study that evaluates long-term cumulative depletion volumes in 40 separate aquifers by using information from the literature and from new analyses (see Figure 3.1-23) (USGS, 2013b). USGS (2013b) has calculated depletion using calibrated groundwater models, analytical approaches, or volumetric budget analyses for multiple aquifer systems. Based on these analyses the estimated groundwater depletion in the U.S. during 1900–2008 totals approximately 1,000 cubic kilometers (km^3). Furthermore, USGS (2013) notes that the rate of groundwater depletion has increased markedly since about 1950, with maximum rates occurring during the most recent period (2000–2008) when the depletion rate averaged almost 25 km^3 per year (compared to 9.2 km^3 per year averaged over the 1900–2008 timeframe). The relevance of documenting the areas of groundwater depletion is that these would be the most affected by shifting of irrigation sources from surface water to groundwater. As shown in Figure 3.1-23, there are several geographical areas where large scale groundwater depletion is evident over agricultural areas with a high percentage of the covered farms (Figure 3.1-23). Significant dewatering is evident over the Central, Coachella and Death Valleys of California; Alluvial Basins of Arizona; and the Columbia Plateau in southeastern Washington and northeastern Oregon (when comparing Figure 3.1-23 with Figure 1.7-4 in Chapter 1.7, these correspond to regions B, C, and D). While Figure 3.1-23 does not show certain aquifers in Texas as being critically stressed, as discussed in Chapter 3.1.3.8, Texas is among the highest agricultural water users in the country (USGS, 2009), and coupled with the arid conditions faced by the state, the opportunities for adequate aquifer recharge are becoming fewer. Therefore, when comparing Figure 3.1-23 with Figure 1.7-4 in Chapter 1.7, the Texas aquifers that encounter problems related to groundwater depletion include those in regions I and J.

When we consider aquifers that are shared transboundary (see discussion in Chapter 3.1.3.7) and that are experiencing stress due to water depletion, aquifers within the Alluvial Basins of Arizona (region D), and those covering portions of Texas, such as the Edwards-Trinity aquifer system (corresponding to regions I and J) are accessed in major produce-growing regions, and are a shared resource with Mexico.[7] Carter et al. reports that several of the transboundary aquifers have experienced substantial declines in volume and/or quality; and while the increasing use of water is a known cause of shared aquifer deterioration (Carter et al., 2011), Eckstein (2013) estimates that the border population is expected to increase to approximately 20 million residents by 2020 (as compared to an estimated 12 million in 2011), which would apply further pressure on the long-term sustainability of those aquifers. Agriculture, industrial use, and population development all contribute to the depletion and deterioration of transboundary aquifer resources (Eckstein, 2011). Climate change also effects groundwater supply, as the U.S.-Mexico

[7] The U.S. Department of the Interior participates in a U.S.-Mexico Border Field Coordinating Committee to facilitate and address cross-border natural and cultural resources issues between the two nations. The coordinating committee, as part of its responsibility, works with educational institutions to study impacts to shared resources, such as aquifers, and to seek resolution to challenges that affect these resources (e.g., climate change, continued pressures from development on the aquifer's water storage capacity). Additional information and ongoing research on transboundary aquifers may be found here: http://www.cerc.usgs.gov/FCC/.

border region is arid to semi-arid and climate change models indicate that the conditions may become even more arid over the next century (USGS, 2013a and Eckstein, 2011).

> An example of substantial groundwater drawdown as cited by Eckstein (2011) includes the Hueco Bolson aquifer, that, between the years 1952 and 2007, the water table along portions of the aquifer fell by an estimated 76 feet. In terms of environmental impacts, in their 2015 Congressional Research Report, Carter et al. found that groundwater pumping along the U.S.-Mexico border region has lowered the water table and reduced the base flow of many streams. Impacts associated with decreasing stream base flow result in a reduction of the quantity of water available to suitably support or sustain riparian habitats. Carter et al. (2015) also found that groundwater drawdown along major urban centers has resulted in land subsidence, and thus, structural damage to urban and residential infrastructure (the author cited the example of the El Paso/Juarez metropolitan region).

Unless otherwise noted, the summary of groundwater development that follows was provided by L. F. Konikow (USGS, 2013b).

The Central Valley of California is a major agricultural area in a large valley with an area of about 52,000 km^2 and includes the Sacramento Valley, the San Joaquin Valley, and the Tulare Basin (Figure 3.1-23). Streamflow is an important factor in the water supply of the valley, and is entirely derived from precipitation in the Sierra Nevada to the east and in parts of the Klamath Mountains in the north.

Groundwater development began in the Central Valley around 1880, and by 1913, total annual well pumpage for the Central Valley was about 0.44 km^3. A sharp increase in pumpage was observed during the 1940s and 1950s, and by the 1960s and 1970s averaged about 14.2 km^3/yr. By the 1980s there were approximately 100,000 high-capacity wells in the Central Valley for either irrigation or municipal supply. In the late 1960s, increased importation of surface water caused groundwater pumpage to decline. However, a drought during 1976–77 decreased the availability of surface water, and groundwater pumpage increased to a maximum of 18.5 km^3 in 1977. Heavy groundwater use in parts of the Central Valley has caused continuous water-level declines. In parts of the San Joaquin Valley and Tulare Basin, water levels had declined nearly 122 m, depleting groundwater from storage and lowering water levels to as much as 30 m below sea level. Long-term water-level records in some wells indicate that water levels were already declining at substantial rates when water levels were first observed as early as the 1930s. The extensive groundwater pumping caused changes to the groundwater flow system, changes in water levels, changes in aquifer storage, and widespread land subsidence in the San Joaquin Valley, which began in the 1920s.

Because of the 2013 drought, Central Valley irrigators face about a one-third reduction or 6.5 million acre feet (maf) in surface water deliveries this growing season, compared with normal years (USGS, 2013b). Growers are likely to increase groundwater pumping to replace about 5 maf of this shortage, leaving 1.5 maf or about 7.5 percent of normal irrigation water use in the Central Valley (USGS, 2014b). In 119 years of recorded history, 2013 was the driest calendar year for the State of California (USGS, 2013b).

The Southwest alluvial basins include an area of 212,000 km^2 in south-central Arizona and small parts of adjacent States (Figure 3.1-23). Development of water resources was principally for agriculture and was started in the 1860s. Groundwater withdrawals began in the late 1800s, and by 1942, groundwater pumpage totaled 2.1 km^3/yr. Rapid agricultural growth followed, and by 1952, groundwater pumpage was 4.7 km^3/yr. During 1950–80, groundwater pumpage averaged more than 5.9 km^3/yr. The withdrawals greatly exceeded recharge, so large water-level declines resulted, generally in the range of 15 to 140 m, but more than 180 m in places. This also resulted in land subsidence. By 1980, a total of 227 km^3 of groundwater had been withdrawn. More than 50 percent of this volume (113.5 km^3) was removed from aquifer storage.

The Columbia Plateau aquifer system in the northwestern U.S. underlies 131,000 km^2 of southeastern Washington, northeastern Oregon, and northwestern Idaho (Figure 3.1-23). It is a productive agricultural area, and a large quantity of water used in the region is derived from local and imported surface-water sources. Groundwater usage is substantial, however, and the Columbia Plateau aquifer system is the primary source of groundwater in the region. Water levels in localized areas within the Columbia Plateau aquifer system have risen as much as 90 meters due to recharge from surface-water imports in areas of heavy irrigation. Groundwater pumping in areas where surface-water imports are not widely used has led to water-level declines of up to about 90 meters (USGS, 2013b). Approximately 80 percent of groundwater withdrawals are used for irrigation purposes, and the remainder is primarily used for municipal and industrial supply.

The major use of water withdrawn in the Columbia Plateau region is for irrigation purposes, and most of the irrigation in the region is supplied by local and imported surface waters. Between 1945 and 1984, about 70 percent of the total water withdrawals were from surface-water sources and that proportion increased to about 74 percent between 1985 and 2007. The water added to the aquifer from percolation of excess irrigation water has significantly expanded the saturated zones in the overburden aquifer and the uppermost permeable basalt unit, which has raised groundwater levels in these areas close to the land surface.

Changes in pump technology and the switch from flood irrigation to sprinkler irrigation greatly increased groundwater use. Nearly 0.22 km3/yr of groundwater was pumped during 1960; nearly 1.2 km3/yr was pumped during 1979. About 1.4 km3/yr was pumped on average between 1984 and 2007.

Water levels rose an average of 12 meters in the overburden aquifer, and water-level rises were as great as 60 meters in areas of heavy irrigation by 1985, though water-rises had stabilized in many areas between the mid-1960s and 1970s. Declines in water levels, however, occurred in much of the deeper basalt units. Water-level records for selected wells showing more recent trends indicate that the rates of change of water levels were often relatively linear from the 1970s through 2000.

In Florida (corresponding to region U), a thick sequence of carbonate rocks (limestone and dolomites) make up the Floridan aquifer system that underlie all of Florida, southern Georgia, and small parts of adjoining South Carolina and Alabama (USGS, 2003a). In addition to water supply, the Floridan is being used for aquifer storage and recovery systems, in which freshwater

is injected into more saline zones of the aquifer and stored for later use. Groundwater withdrawals have resulted in long-term regional water-level declines of more than 10 ft. over broad areas of the flow system (Figure 3.1-24). In these areas groundwater withdrawals have reversed the generally seaward direction of groundwater flow, creating the potential for saltwater intrusion from the Gulf of Mexico or Atlantic Ocean or from deep parts of the aquifer that contain saltwater.

The transition between freshwater and saltwater in the Floridan aquifer system is illustrated by the distribution of chloride in water in the Lower Floridan aquifer (Figure 3.1-25) where much of the Lower Floridan aquifer contains water with chloride concentrations that exceed the 250 milligrams per liter (mg/L) drinking-water limit, which has limited the aquifer's use for water supply.

Figure 3.1-23. Map of the U.S. showing cumulative groundwater depletion, 1900 through 2008, in 40 assessed aquifer systems or subareas. (USGS, 2013b)

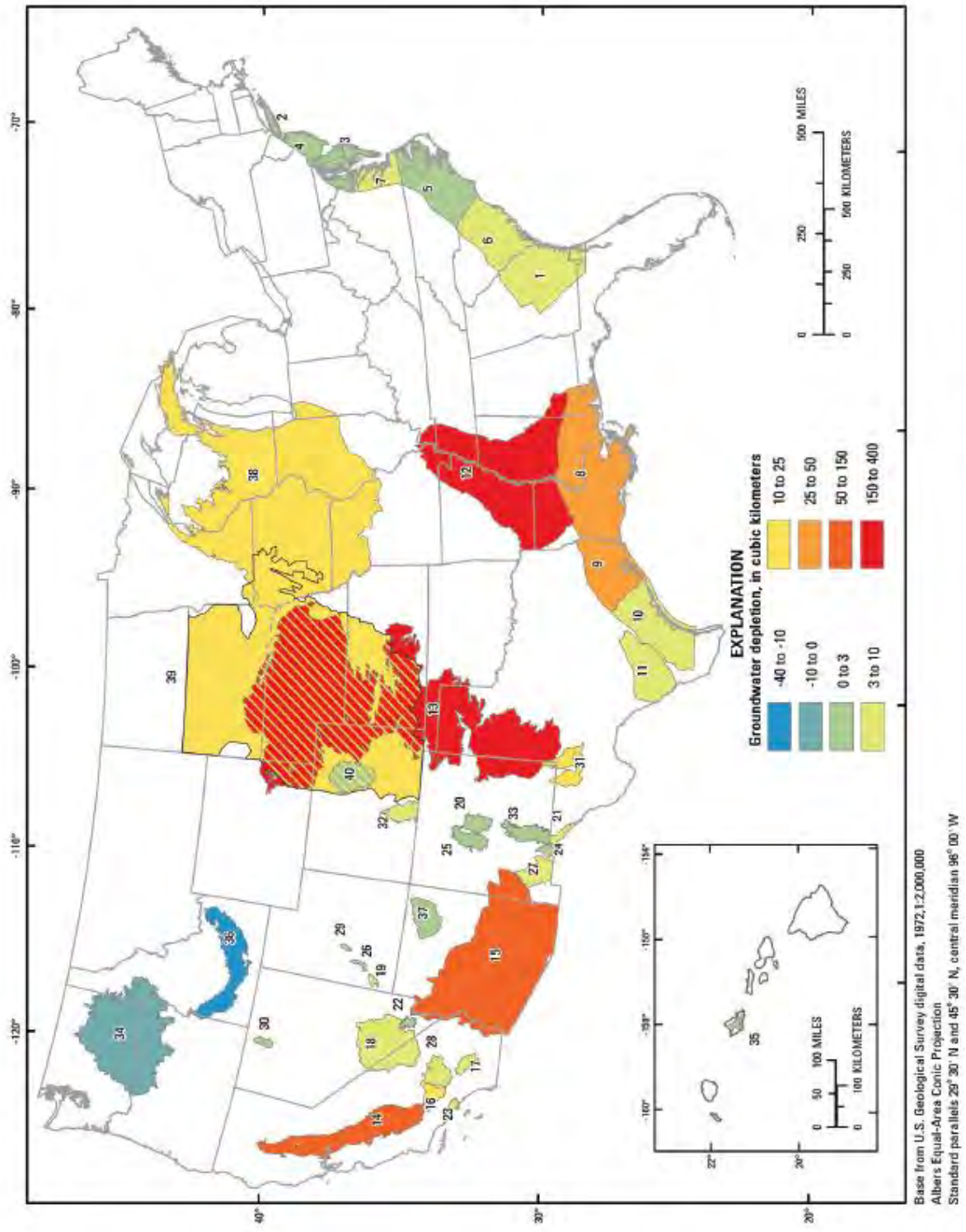


Figure 3.1-24. Areas of large, regional water-level declines in the Floridan aquifer system (USGS, 2003a)

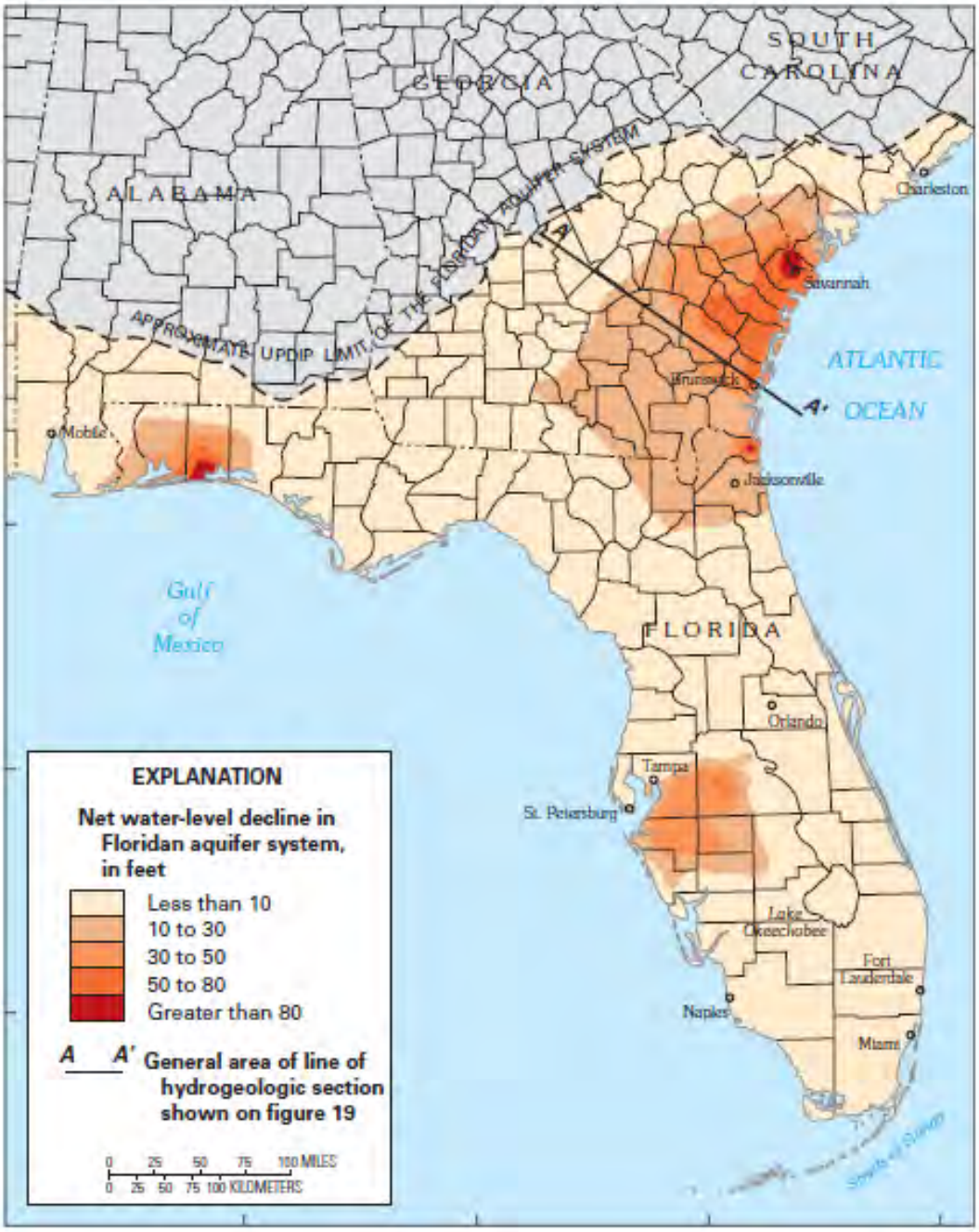
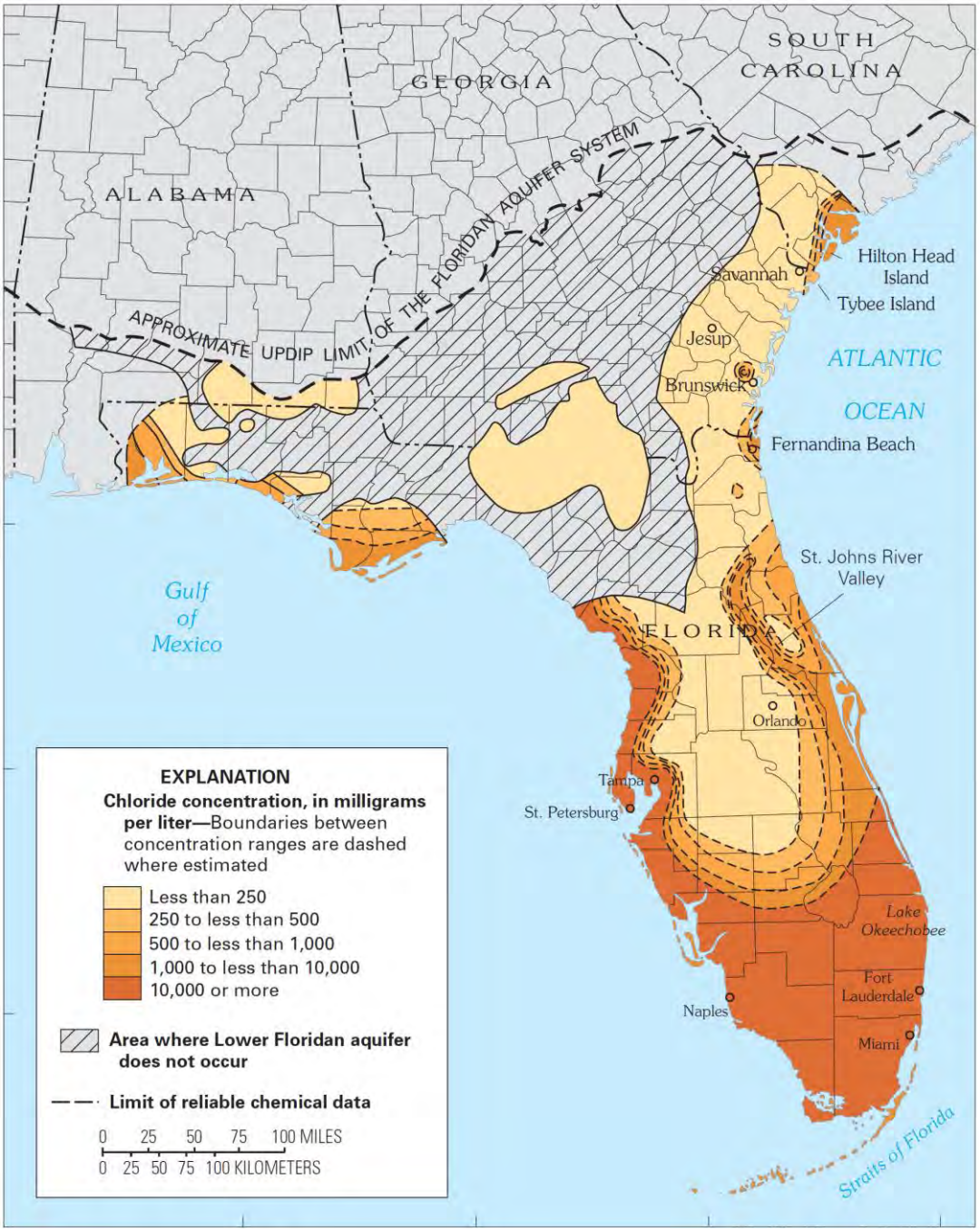


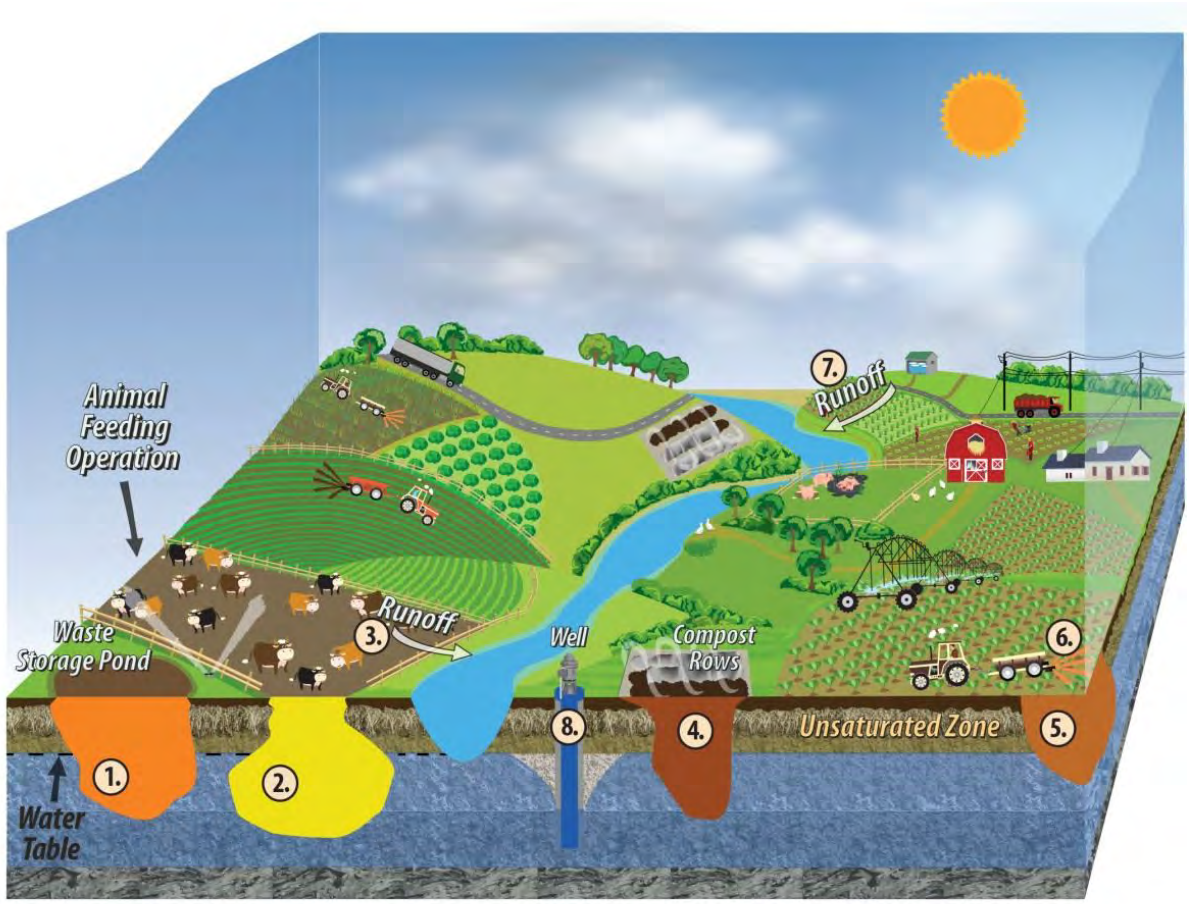
Figure 3.1-25. Chloride concentrations in water from the Lower Floridan aquifer (USGS, 2003a)



Conceptual Site Model

Figure 3.1-26 represents the types of activities on a working produce farm that could affect water resources.

Figure 3.1-26. Conceptual site model for water resources



The Key below contains text that applies to numbered key components of the diagram.

Key to numbered illustrations within Conceptual Site Model (Figure 3.1-26)	
1	● Infiltration from waste storage ponds may lead to groundwater contamination.
2&3	● Wastes concentrated in animal feeding operations may infiltrate to groundwater or be carried in surface water runoff to streams.
4	● Leaching of compost may result in localized sources of groundwater contamination.
5&6	● Fertilizer and pesticides can migrate to groundwater.
7	● Erosion of soil and runoff of fertilizer from cultivated or fallow fields may be a source of surface water contamination.
8	● Groundwater pumping will lower the water table and may lead to reduced stream flow.

3.2 Biological and Ecological Resources

3.2.1 Definition of the Resource

Biological and Ecological Resources include vegetation, terrestrial, avian, and aquatic species, including protected species, within agricultural lands and adjacent "off-farm" areas. Vegetation includes both native and non-native plant species, such as major agricultural crops, invasive species, and noxious plant species. Wildlife species include both native and non-native species. Wetland resources are also discussed in this section.

Vegetation

Vegetation resources throughout the Nation provide valuable environmental, economic, and recreational functions. Environmental functions include, but are not limited to, the provision for requisite habitats for wildlife, erosion control and water quality enhancements, and air quality enhancements. The presence of vegetation also provides substantial economic benefits (e.g., lumber) and recreational opportunities in the form of natural areas for hiking, camping, wildlife observation, and hunting.

The vegetation resources most associated with farming operations are generally located adjacent to or abutting the production fields. On a national level, this vegetation is varied and may include hedgerows between production fields, large forested corridors, wet meadows not suited to commercial agriculture, and buffers adjacent to stream channels and lakes.

Non-native vegetation may become a nuisance in certain situations and its presence may have a detrimental effect on the local ecosystem. If vegetation becomes invasive, it changes the vegetated community and possibly no longer provides the life requisites for native wildlife species. The federal government and many states have enacted laws and regulations addressing the impacts of non-native plant species, including the development of lists of nuisance and invasive plant species. Farming operations by their very nature are often plagued by nuisance and invasive plant species adjacent to and within their production fields.

Wildlife

Wildlife species are important participants in the web of life; fulfilling roles necessary for healthy and successful ecosystems. Many of these species are protected by a patchwork of federal, state, and local laws designed to manage the overall environmental health and economic sustainability of wildlife resources. Because most wildlife species are mutually reliant and interdependent on other species within the ecosystem, the health of the entire system is important.

Mammals are present in all habitat types throughout the U.S., including agricultural lands. Farm operations and their associated habitats provide shelter, food, water, and breeding opportunities for many species of mammals. Some species have small ranges and may not leave the areas that are actively farmed, while other species have much larger territories and will use farmed areas for just a portion of their life requisites.

There are more than 800 species of birds in the U.S. (Audubon, 2014). These birds have varied sizes of home ranges, dependent on the species. Farms and their adjacent habitats provide shelter, food, water, and nesting for many of these bird species.

Many avian species are protected by various federal and state laws. The Migratory Bird Treaty Act of 1918 (MBTA, 16 U.S.C. § 703 et seq.) established the federal prohibition, unless permitted by regulations, to "pursue, hunt, take, capture, kill, attempt to take, capture or kill, possess, offer for sale, sell, offer to purchase, purchase, deliver for shipment, ship, cause to be shipped, deliver for transportation, transport, cause to be transported, carry or cause to be carried, or receive for shipment, transportation, carriage, or export, any migratory bird, and any part, nest, or egg of any such bird" (16 U.S.C. § 703(a)). Non-migratory bird species and their habitats are also protected by various federal and state laws.

Fish species and other aquatic organisms are present throughout the U.S., including in farm environments. In addition to being a valued part of the food web, many fish and other aquatic species are economically valuable. Amphibians, reptiles, and invertebrate species are also present throughout the U.S., including in farm environments.

Threatened and Endangered Species

Protected species are plants and animals listed (i.e., endangered or threatened) by the federal government as needing protection because of their population status. The Endangered Species Act of 1973 (ESA, 16 U.S.C. § 1531 et seq.) prohibits the "taking" of threatened or endangered species without a permit. The term "take" means "to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct" (16 U.S.C. § 1532(19)).

An endangered species classification is provided to an animal or plant in danger of extinction within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. § 1532(6)). A threatened species classification is provided to any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. § 1532(20)). The number of animal species listed as either endangered or threatened in the U.S. is 671 and the number of plant species listed as either endangered or threatened in the U.S. is 879 (USFWS, 2014a). Table 3.2-1 depicts the number of federally listed threatened and endangered plant and animal species by state.

As discussed in Chapter 4 (subsection for *Resource components not included for review in the EIS),* FDA, in the PS PR, refers growers of produce to the FWS's Endangered Species Web site and the Information, Planning, and Conservation System Web site. FDA further recommends that a grower coordinate with its local FWS office on any activity that could potentially affect listed species or critical habitat (79 Fed. Reg. 58434 at 58464). See Chapter 4 for additional information on this issue.

Table 3.2-1. Federally-listed Plant and Animal Species by State, 2014 (USFWS, 2014b)

State	Total Plants	Total Animals	Total Plants and Animals	State	Total Plants	Total Animals	Total Plants and Animals
Alabama	19	109	128	Montana	3	10	13
Alaska	1	21	22	Nebraska	5	15	20
Arizona	21	45	66	Nevada	10	35	45
Arkansas	6	31	37	New Hampshire	3	13	16
California	188	136	324	New Jersey	7	18	25
Colorado	16	19	35	New Mexico	13	40	53
Connecticut	3	16	19	New York	11	23	34
Delaware	7	15	22	North Carolina	27	42	69
Florida	58	71	129	North Dakota	1	7	8
Georgia	24	54	78	Ohio	6	28	34
Hawaii	368	69	437	Oklahoma	3	20	23
Idaho	4	16	20	Oregon	19	50	69
Illinois	10	32	42	Pennsylvania	6	22	28
Indiana	5	32	37	Rhode Island	3	14	17
Iowa	5	16	21	South Carolina	21	27	48
Kansas	3	18	21	South Dakota	1	10	11
Kentucky	9	44	53	Tennessee	20	83	103
Louisiana	4	29	33	Texas	31	75	106
Maine	3	14	17	Utah	25	18	43
Maryland	10	20	30	Vermont	3	7	10
Massachusetts	5	21	26	Virginia	18	59	77
Michigan	8	16	24	Washington	12	46	58
Minnesota	4	12	16	West Virginia	6	22	28
Mississippi	4	48	52	Wisconsin	7	14	21
Missouri	10	29	39	Wyoming	4	12	16

Figure 3.2-1 and Figure 3.2-2 depict the numerical range of listed plant and animal species that occur by state.

Figure 3.2-1. Map of the U.S. depicting the numerical range of Threatened or Endangered Plant Species by State.

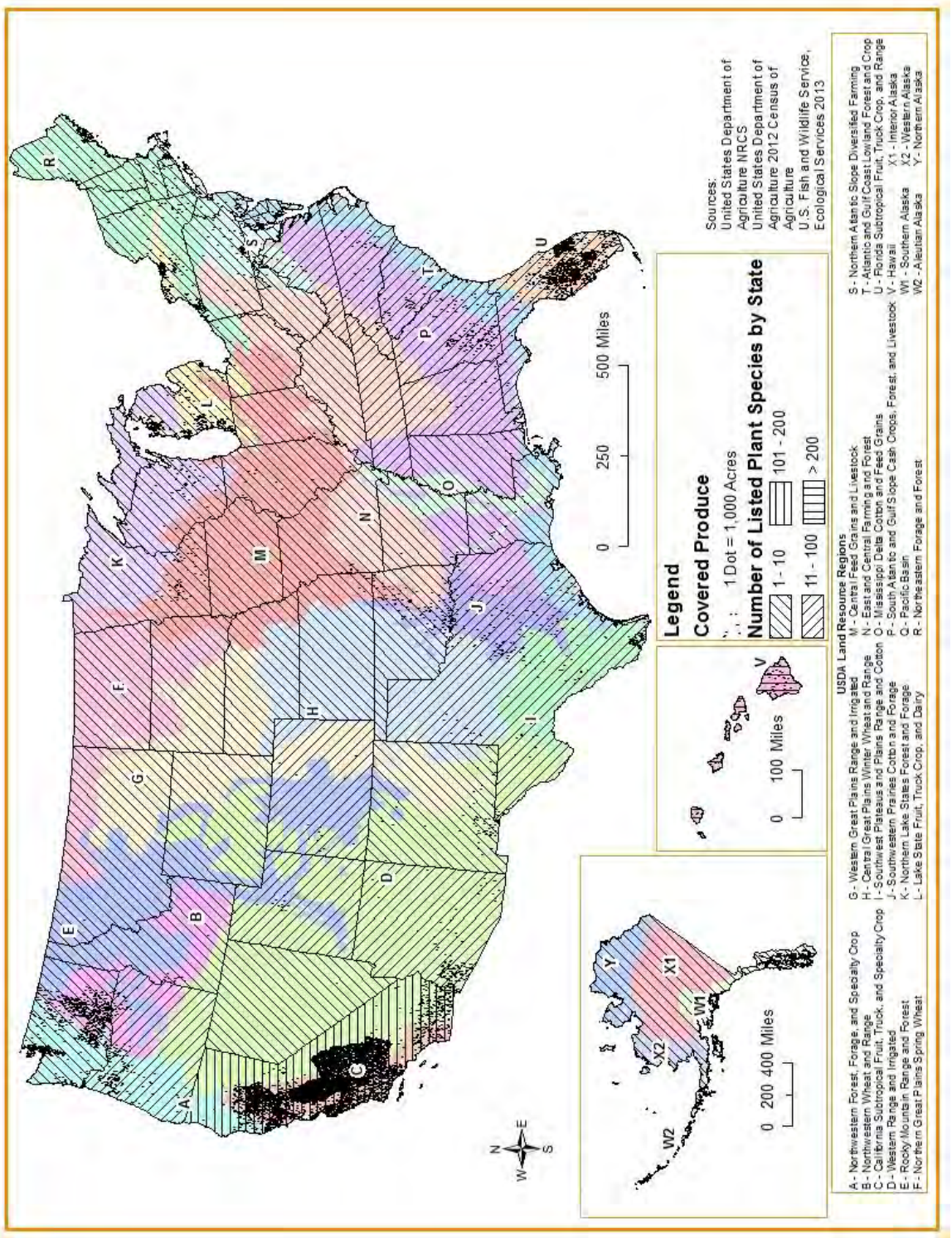
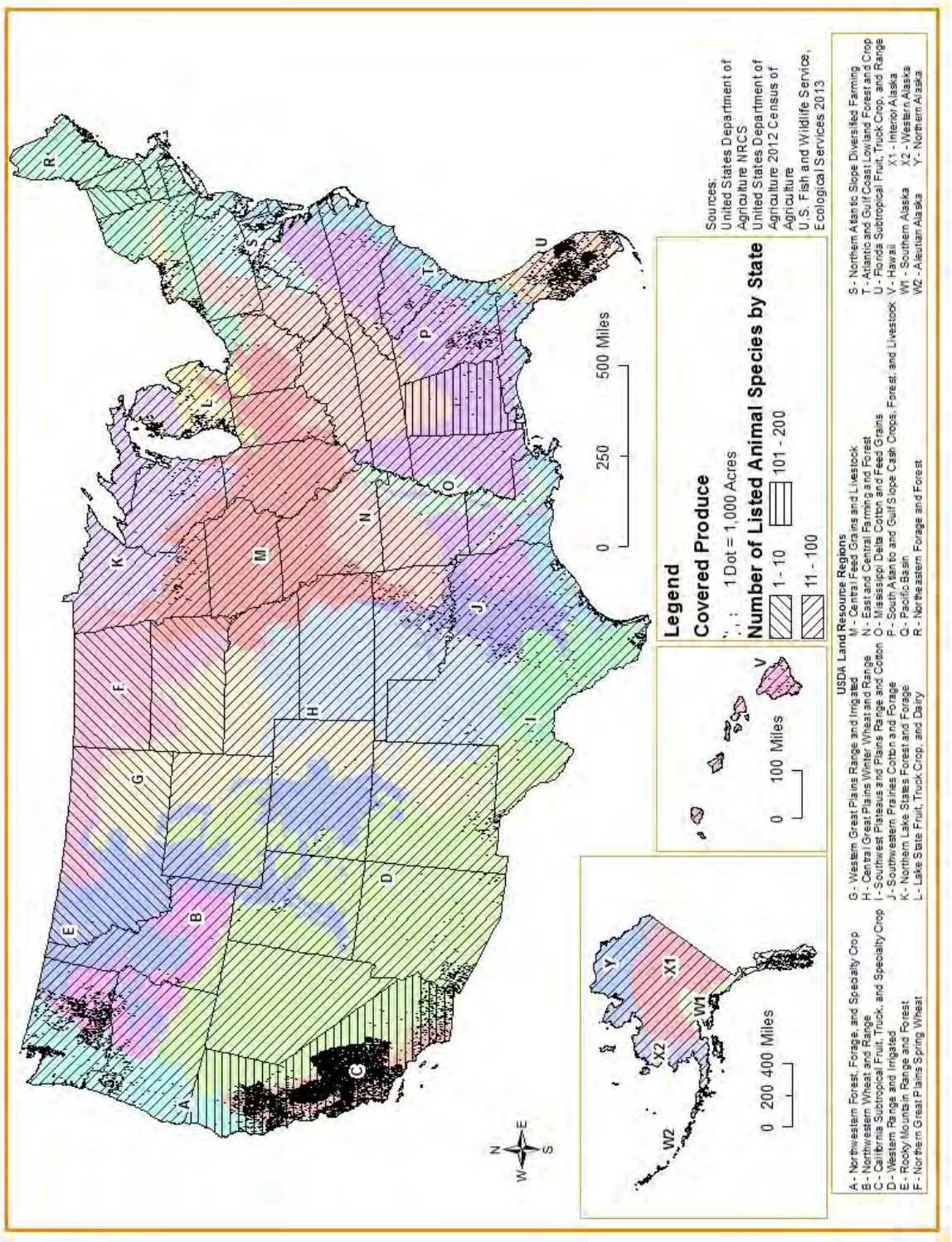


Figure 3.2-2. Map of the U.S. depicting the numerical range of Threatened or Endangered Animal Species by State.



Wetlands

Wetlands are valuable resources that perform many functions, including but not limited to, providing habitat for plants and many forms of wildlife, clean water, and flood protection. Wetlands usually occur at the transition between an aquatic system and a terrestrial system and often have saturated soil for all or most of the growing season. There are many types of wetlands in the U.S., including marshes, swamps, and bogs.

The CWA established the basic structure for regulating discharges of pollutants into the waters of the U.S., including wetlands, and regulating quality standards for surface waters. The CWA requires a permit (applicable to public and private actions) be obtained prior to impacting a jurisdictional wetland or other water of the U.S. (33 U.S.C. §§ 1341-1346). Many states also have laws protecting wetland resources.

In 2009, it was estimated that 110.1 million acres of wetlands existed in the Conterminous U.S. (USFWS, 2011). It has been estimated that over 220 million acres of wetlands existed in the Conterminous U.S. in the 1600s, meaning that over 50% of the original wetlands have been drained or converted to other uses between the 1600s and 2009 (EPA, 2013a). Current wetland protection measures have slowed the conversion of wetlands to other land use types (EPA, 2013a).

3.2.2 Regulatory Oversight

Statutory and regulatory requirements at the federal and state levels are often associated with the use and management of biological and ecological resources. Federal laws include but are not limited to the NEPA, the ESA, the MBTA, and the CWA. Federal agencies responsible for the management of biological and ecological resources include, the EPA, the USFWS, the National Oceanic and Atmospheric Administration/National Marine Fisheries Service (NOAA/NMFS), and the U.S. Army Corps of Engineers (USACE). Each state has its own laws and regulations pertaining to the biological and ecological resources within its borders.

3.2.3 Current Background Conditions

With the exception of federally listed threatened and endangered species, inventories of vegetation and animal species do not exist on a national level. Some state, regional, and local areas throughout the U.S. maintain lists of flora; however, a comprehensive national database of plant species does not exist. Similarly, animal species data has not been compiled on a national basis. Due to the lack of a comprehensive data set on the presence and distribution of non-listed species, a rigorous analysis of this resource type is not possible.

The National Wetland Inventory, through the USFWS, and several state natural resource agencies maintain inventories of wetland resources throughout the nation. Much of this data is provisional and requires that actual site investigations occur to confirm the presence or absence of wetland resources. In addition, not all wetland resources are jurisdictional (i.e., subject to

regulatory control); therefore, any quantities of wetland resources present on a national level, are estimates.

Biological and ecological resources and agricultural water

Biological and ecological resources require water to be available for their sustainability. Water is a life requisite and any change in the quantity or quality of available water may pose a threat to these resources. Once water is used for agricultural purposes, a portion of that water may re-enter the groundwater and surface water ecosystems. The quantity, quality, and fate of the used agricultural water on a local level may be altered from current conditions to a level that changes the interactions of biological and ecological resources with available water supplies.

Biological and ecological resources and biological soil amendments

The use of biological soil amendments in agricultural operations may add nutrients and possibly other contaminants to the ecosystem. If excess nutrients or other contaminants are allowed to enter surface or groundwater, the ecosystem may be altered, favoring one group of organisms over another. However, the addition of organic matter to the soil that typically comes from the use of biological soil amendments generally improves soil health, arability, and tilth, allowing water to soak into the soil and minimizing runoff of agricultural water or precipitation. This improvement in soil quality, and the associated possible reduction in runoff and sedimentation of surface waters, typically contributes to ecosystem health.

Biological and ecological resources and domesticated and wild animals

Agricultural operations are not natural ecosystems (i.e., they are intensively manipulated for the benefit of humans); however, they do provide habitat and other life requisites for many species of plants and animals. The intrusion (grazing) of domesticated and wild animals into farming operations may provide feeding opportunities superior to those found outside of farmed areas, for some species, at specific times of the year.

Biological and ecological resources and businesses covered by the PS PR

The farming operations to be exempted by the PS PR constitute a very small portion of the total farmed acreage of the United States. Therefore, most of the currently farmed acreage will continue to interact with the biological and ecological resources of the nation.

3.3 Soils

3.3.1 Definition of the Resource

A key issue identified for soil resources is maintenance of the natural biological integrity of the soil, which can be interpreted as maintenance of soil health. A primary public concern of agricultural soil health is the reduced use of manure as a nutrient source for soil and the increased use of nitrogen-based synthetic soil amendments. The NRCS in its presentation "Unlock the Secrets in the Soil" (USDA NRCS, 2013a) describes soil health as the continued capacity of the soil to function as a vital living ecosystem that sustains plants, animals and humans. These functions are further identified as follows:

- **Nutrient Cycling** - Soil stores, moderates the release of, and cycles nutrients and other elements. During these biogeochemical processes, analogous to the water cycle, nutrients can be transformed into plant available forms, held in the soil, or even lost to air or water.

- **Water Relations** - Soil can regulate the drainage, flow and storage of water and solutes, which includes nitrogen, phosphorus, pesticides, and other nutrients and compounds dissolved in the water. With proper functioning, soil partitions water for groundwater recharge and for use by plants and soil animals.

- **Biodiversity and Habitat** - Soil supports the growth of a variety of plants, animals, and soil microorganisms, usually by providing a diverse physical, chemical, and biological habitat.

- **Filtering and Buffering** - Soil acts as a filter to protect the quality of water, air, and other resources. Toxic compounds or excess nutrients can be degraded or otherwise made unavailable to plants and animals.

- **Physical Stability and Support** - Soil has the ability to maintain its porous structure to allow passage of air and water, withstand erosive forces, and provide a medium for plant roots. Soils also provide anchoring support for human structures and protect archeological treasures.

3.3.2 Regulatory Oversight

There are few federal regulations that govern agricultural soil and conservation. The Farmland Protection Policy Act (FPPA) (7 U.S.C. §§ 4201-4209) was enacted in order to protect farms that may be subjected to federal programs from the unnecessary and possible irreversible conversion of farmland to nonagricultural purposes.[8]

[8] Note that FDA's proposed rule does not require farms to be converted in any way from their current agricultural use.

3.3.3 Current Background Conditions

The source of basic scientific understanding and information used to develop and support the analysis of soil resources include:

- Databases and research activities from USDA Agriculture Research Service and Western Center for Food Safety at University of California Davis;
- USDA Cooperative Research and Extension Services;
- Research activities from land grant universities (Cornell, Purdue, Michigan State, University of Minnesota etc.); and,
- State-specific guidance documents.

The use of BSAs of animal origin, unless otherwise specified in the form of raw or composted, is regularly applied to agricultural land to improve soil fertility and structure. Manure's fertilizing value is significant in that it supplies all major nutrients [nitrogen (N), phosphorus (P), potassium (K), calcium (Ca), magnesium (Mg), and sulfur (S)] necessary for plant growth as well as micronutrients; additionally, degraded soils can be revitalized by adding manure or compost. In addition to prevailing climate and hydrological conditions, studies have determined that the effects of manure and, in particular, the fate of microorganisms on the environment are strongly influenced by the soil conditions. With approximately 4,473,575 acres of vegetable crops harvested for sale (USDA NASS, 2014a) and more than 573,016 vegetable crop acres (USDA NASS, 2014a) that are potentially utilizing all forms of manure for its fertilizing value, understanding the role of soils and the conditions that facilitate the transport of pathogens from the BSA to the food chain is vital. Agricultural disturbances that are recognized as destroying dynamic soil properties include tillage/compaction (physical properties), synthetic fertilizer/misuse of soil amendments (chemical properties) and overgrazing/lack of plant diversity (biological properties) (USDA NRCS, 2013a; Brady and Weil, 2002; Magdoff and van Es, 2009).

3.3.3.1 Overview of Soil Characteristics and their Influence on Transport of Pathogens

A view of the soil orders map of the U.S. with areas of vegetable production graphically demonstrates the variation of soils across the country at the highest level (Figure 3.3-1). It also shows commonality that exists within regions of the country. The same factors of parent material, organisms, climate, relief and time that determined soil formation are the same factors that are still influencing the soil as a medium and effects how specific soils will affect the survival and movement of microorganisms and subsequently the effectiveness of specific management practices. Therefore, comprehension of these underlying soil forming factors may be important for anticipating the range of conditions that relate to the pathogenic transport in the soils environment.

Commonalities from the soil order level are expressed through the various modeling scales shown in Figure 3.3-2 (core, pedon, hillslope, and watershed). The testing of hypotheses about mechanisms and factors of pathogen transport are performed by taking multiple core soil samples and pedon scale (see illustration on next page), and the results are applied to the model and addressed at the hillslope and watershed scales (Pachepsky et al., 2006).

Figure 3.3-1. Dominant soil orders

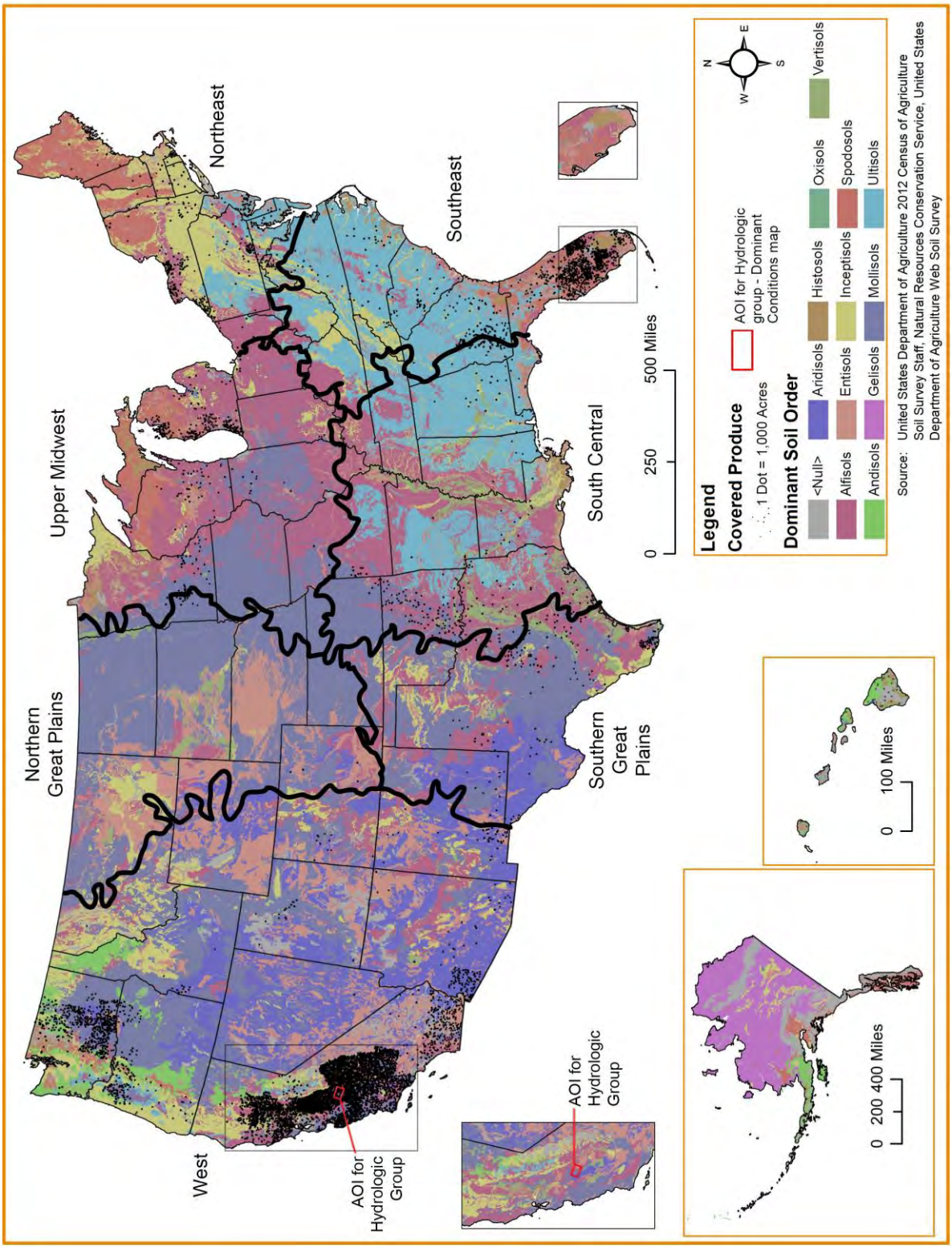


Figure 3.3-2. Scales for modeling manure-borne pathogen transport (Pachepsky et al., 2006)

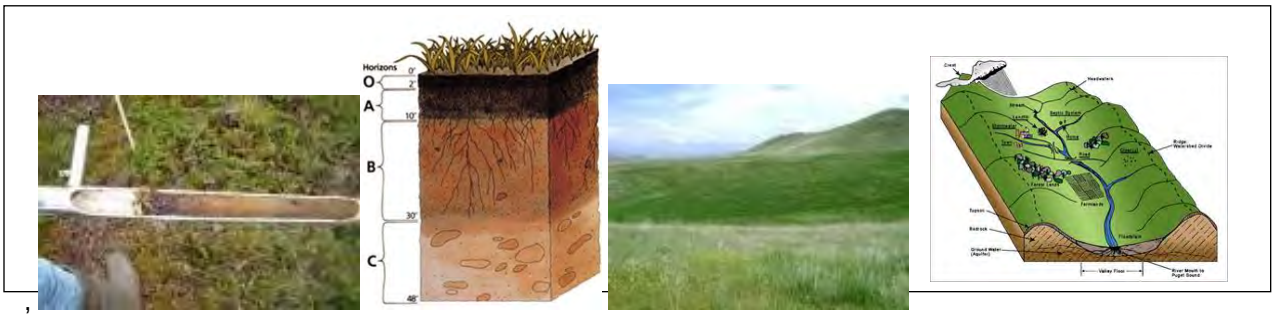


Figure 3.3-3 demonstrates the information flow in coarse-scale models of manure-borne pathogen transport (Pachepsky et al., 2006) and indicates that pathogen release is very interrelated with soils from soil management to soil properties and is also influenced by vegetation and topography.

Figure 3.3-3. Example of coarse-scale pathogen fate transport model

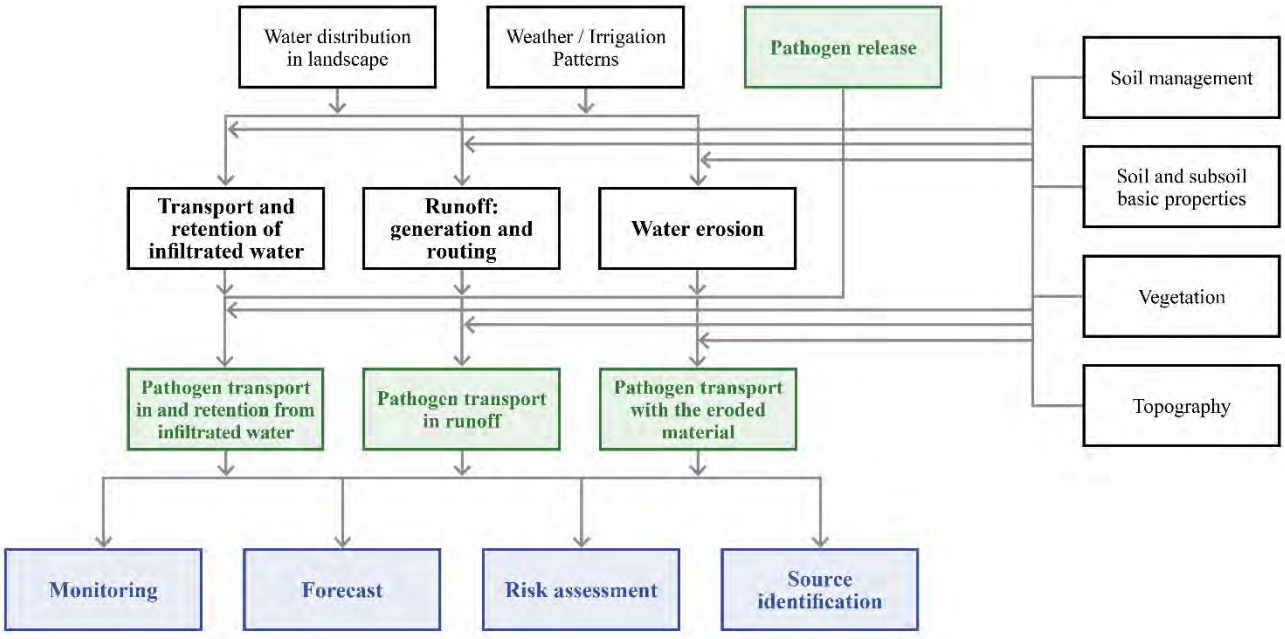


Table 3.3-1 and Table 3.3-2 provide some details of the factors and their effect on the survival and the movement of enteric bacteria and viruses in soil. It demonstrates the variability of factors and indicates the dynamic conditions that influence the process which affects the ability to make broad assumptions. As such these factors are defined as components of studies that are needed to enhance the understanding of the pre-harvest microbial food safety hazard and control measures pertaining to the application of untreated soil amendments (Harris et al., 2012).

Table 3.3-1. Factors affecting survival of enteric bacteria and viruses in soils

	Factor	Comments
Physical and Chemical Nature of Receiving Water	pH	Shorter survival time in acidic soils (pH 3-5) than in alkaline soils
	Soil water content	Longer survival time in wet soils and during times of high rainfall
	Organic matter content	Increased survival and possible growth when sufficient amount of organic matter is present
	Texture and particle size distribution	Finer soils especially clay minerals and humic substances increase water retention by soil, which increases survival time
	Temperature	Longer survival at lower temperature
	Availability of nutrients	Increase survival times
	Adsorption properties	Microorganisms appear to survive better in sorbed state
Atmospheric Conditions	Sunlight	Shorter survival time at the soil surface
	Water (vapor & precipitation	Longer survival time in wet soils and during times of high rainfall
	Temperature	Longer survival at lower temperature
Biological Interaction	Competition from indigenous microflora	In sterile soil, survival is increased
	Antibiotics	Many microorganisms cannot survive in the presence of antibiotics

Source: Abu-Ashour et al. (1993)

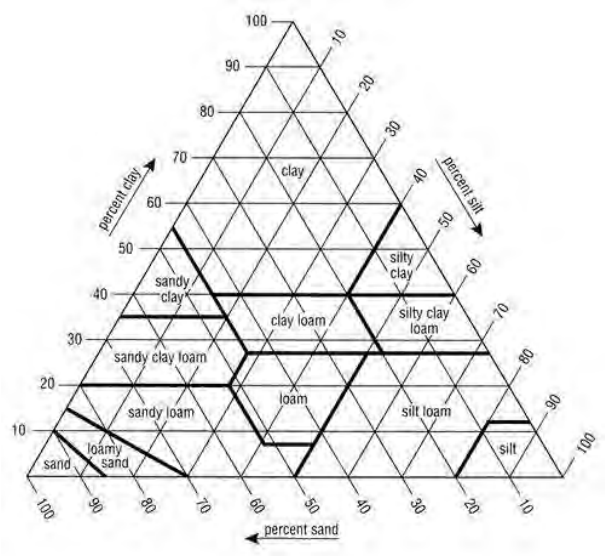
Table 3.3-2. Factors affecting movement of enteric bacteria and viruses

Soil Physical Characteristics	Chemical and Microbial Factors
• Texture • Particle size distribution • Clay type and content • Organic matter type and content • pH • Pore size distribution • Bulk density	• Ionic strength of soil solution • pH of filtrating water • Nature of organic matter in waste effluent solution (concentration and size) • Type of microorganism • Density and dimension of the microorganism
Soil Environment and Chemical Factors	**Application Method**
• Temperature • Soil water content • Soil water flux	• Soil drying between applications • Time of application (winter, spring)

Source: Abu-Ashour et al. (1993)

Influence of Soil Texture

Figure 3.3-4. Soil texture classification



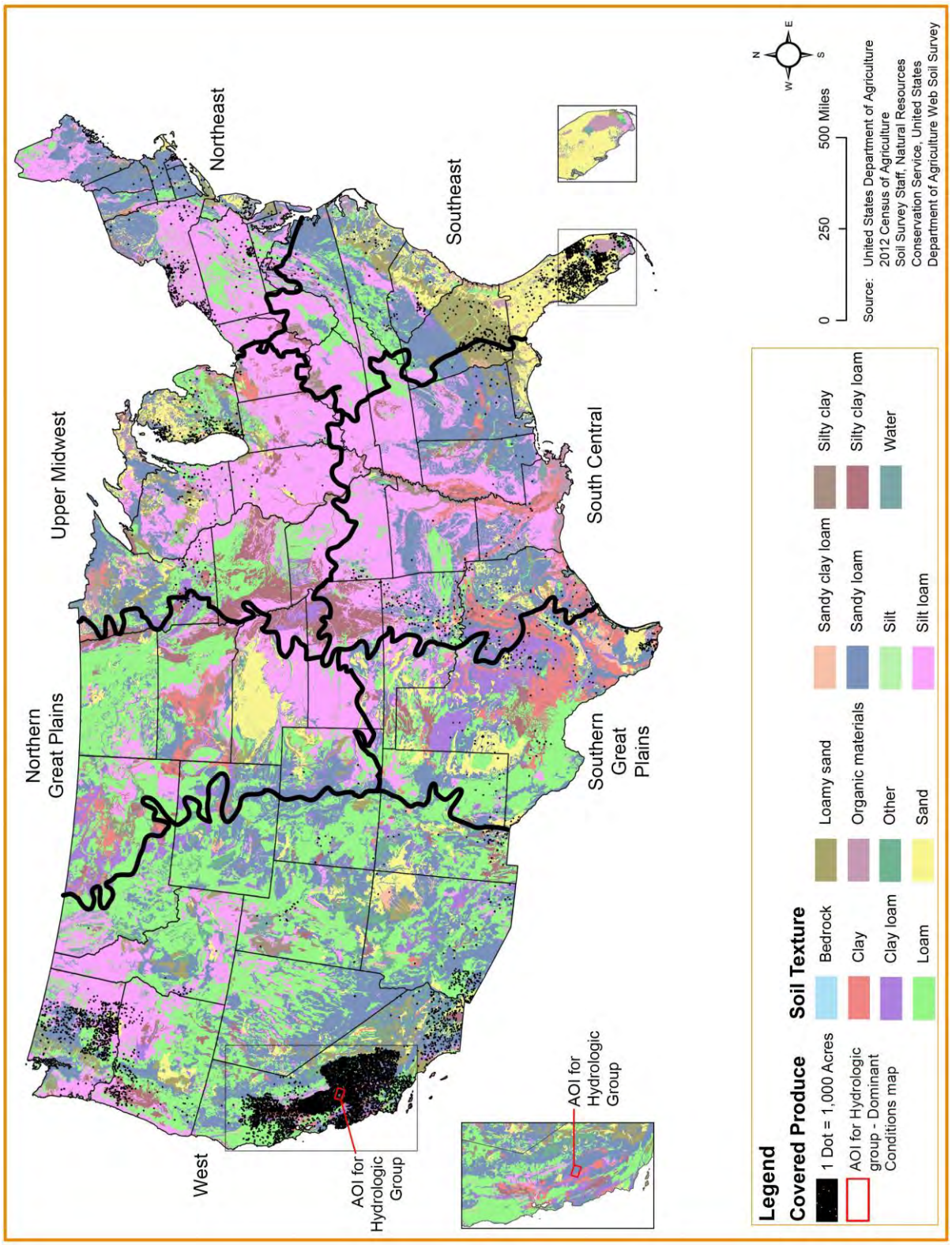
United States Department of Agriculture, NRCS

The relative combination of sand, silt, and clay in a soil defines its texture (Figure 3.3-4). Soil texture is important to classify because it determines or influences many other properties, such that medium and fine sands are transported easily through wind processes, and therefore, the wind is a substantial contributor to erosion. Silts and very fine sands easily help to retain or hold water and make it available for plants longer, but these soils are also easily eroded by water. Clay soils have a very low permeability characteristic and therefore, it holds large amounts of plant nutrients; but it may also lead to drainage and tillage problems. (Purdue University, 2014).

Texture is also important to microbes in that soil texture plays a role in pathogen transport. Microbes and soil particles can interact to form soil aggregates. These aggregates help to bind soils together and reduce surface soil loses to wind and water erosion. Furthermore, soil texture may influence pathogen survival in that pathogens may absorb to soil particles and are offered a greater degree of protection. Pathogens in the unsaturated (vadose) aerobic zone inactivate more rapidly than in the saturated zone because the lack of soil moisture is not conducive to pathogen survival. Also, pathogens in the saturated zone may move more rapidly with water in the soil pore spaces (Cave and Kolsky, 1999). Studies suggest that the single soil property that has the greatest impact on bacterial survival is moisture retention, which is linked to particle distribution and organic matter content (Jamieson et al., 2002).

Figure 3.3-5 shows the distribution of soil textures within the vegetable producing areas throughout the U.S. and the figure illustrates that there are regional commonalities. Dominant textures in the northeast region are silt loam and sandy loam; in the southeast they are dominantly sand, loamy sand and sandy loam; textures in the upper Midwest are dominantly silt loam, silt, sandy loam, silty clay loam; textures in the northwest are dominantly silt loam, silt and sand; and in the west textures are sandy loam, clay, silt clay loam and silt. Studies have shown that moisture is a major factor in determining survival of pathogens and that survival in all types of soil was found to be the greatest in the rainy season (Abu-Ashour et al., 1993). According to Ball (2001), the capacity for soils to hold water is primarily controlled by soil texture and the presence of organic matter in the soils. Soils with smaller particles such as silt and clay, have more surface area than soils with larger sandy particles. The larger surface area of silts and clays allows a soil to hold more water; therefore, there is a higher potential for pathogen survival.

Figure 3.3-5. Soil texture



Soil Drainage Classes

As presented above texture and moisture are interrelated factors that significantly influence the transport of pathogens in the soil. Soils in the U.S. are assigned to drainage classes that provide a guide to the limitation and potential uses of the soil. Achieving a better understanding of the relationship between these parameters and pathogens can provide guidance that is adaptive to regional and local conditions. Figure 3.3-6 illustrates drainage classes within the vegetable producing area in California, which correlates to the dominant soil textures of clay and sandy loam. The drainage classes shown in Figure 3.3-6 are further described in Table 3.3-3.

Figure 3.3-6. Drainage class within vegetable producing area of California

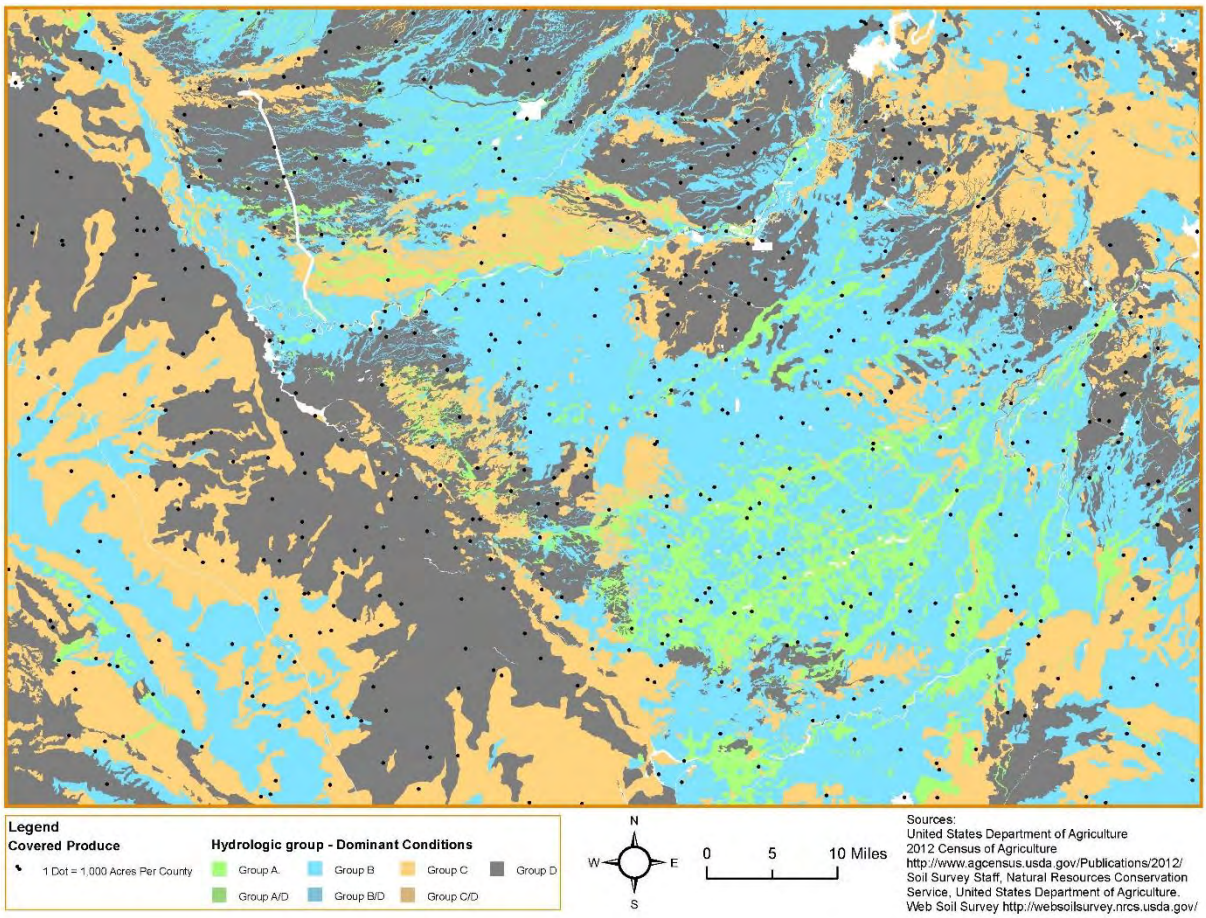


Table 3.3-3. Soil drainage classes

Drainage Classes	Description
Group A	Soils having a high infiltration rate (low runoff potential) when thoroughly wet. These consist mainly of deep, well drained to excessively drained sands or gravelly sands. These soils have a high rate of water transmission.
Group B	Soils having a moderate infiltration rate when thoroughly wet. These consist chiefly of moderately deep or deep, moderately well drained or well drained soils that have moderately fine texture to moderately coarse texture. These soils have a moderate rate of water transmission.
Group C	Soils having a slow infiltration rate when thoroughly wet. These consist chiefly of soils having a layer that impedes the downward movement of water or soils of moderately fine texture or fine texture. These soils have a slow rate of water transmission.
Group D	Soils having a very slow infiltration rate (high runoff potential) when thoroughly wet. These consist chiefly of clays that have a high shrink-swell potential, soils that have a high water table, soils that have a claypan or clay layer at or near the surface, and soils that are shallow over nearly impervious material. These soils have a very slow rate of water transmission.
If a soil is assigned to a dual hydrologic group (A/D, B/D, or C/D), the first letter is for drained areas and the second is for undrained areas. Only the soils that in their natural condition are in group D are assigned to dual classes.	

3.3.3.2 Transport Through Soil

As listed in the tables above there are many factors that influence the fate and transport of pathogens in the soil. However, unlike most chemical pollutants or nutrients such as nitrogen and phosphorus, a typical bacterial pathogen can be as large as five micrometers long, and would therefore experience difficulty moving between the clay or silt particles of many soils high in clay and silt sized particles. Most pathogens therefore travel across the soil surface in runoff water and infiltrate only partially into the soil pores before being captured in the pore space or by adhering to soil particles. Only in sandy soils is the pore space large enough to provide ample traveling space for bacterial pathogens. Even there, pathogens frequently collide onto grain surfaces where they tend to become permanently attached (eXtension, 2007). Therefore, the extrinsic factors that influence microbial transport through soil are summarized as follows:

- Ease of transport through soil is generally in the order of sand, silt and clay;
- Smaller microbes moves more easily through soils;
- Movement is greater in saturated soil than unsaturated soils;
- Since microbes are generally negatively charged and move with soil solution; and,
- Organic matter can increase pathogen survival through formation of biofilms that allow for re-suspension of pathogens.

Understanding those mechanisms that affect movement and pertinence of these pathogens in soils is not only critical in determining the potential effectiveness of application intervals for BSAs but also for providing the framework for the ability to make reasonable assumptions about the effectiveness of controls applied to different regions, conditions, and practices.

Effects of Soil Temperature

Jiang et al. (2002) reported that STEC survived in manure-amended sandy loam soil for at least two months to over six months (56, 152 and 193 days at 5°, 15°, and 21°C, respectively). *Salmonella* persisted in hog manure-amended loamy sand and clay soils for more than 180 days during the simulated summer-winter season as compared with less than 160 days in a spring-summer or winter-summer regime (Millner, 2014). Tables 3.3-4 and Table 3.3-5 demonstrate varying reports for pathogen survival and effect of temperature.

Table 3.3-4. Temperature and pathogen persistence

Survival			
Pathogen		**Survival time on crops at 20-30° C**	**Survival time in soil at 20-30° C**
Viruses	Enteroviruses	<60 days, but usually <15	<100 days, but usually <20
Bacteria	Fecal Coliforms	<30 days, but usually <15	<70 days, but usually <20
	Salmonella	<30 days, but usually <15	<70 days, but usually <20
	Vibrio Cholerae	<10 days, but usually <2	<20 days, but usually <10
Protozoa	*Entamoeba Histolytica*	<10 days, but usually <2	<20 days, but usually <10
Helminths	*Ascaris lumbricoides*	60 days, but usually <2	Many months

Source: WHO (1989)

Influence of Microbial Activity

Jiang and Shepherd (2009) summarized studies that revealed that soil with less ambient soil microbial activity allows the extended survival of manure-borne enteric pathogens; directly attributable to less competition from the indigenous soil microflora (IFT and FDA, 2001; Jiang et al., 2002). For example the studies they used have shown that pathogenic microbes from contaminated manure survived longer in sterilized soil than in native (unsterilized) soil; (e.g., pathogens detectable for 107 days in unsterilized soil versus 158 days when mixed with sterilized soil) (Jiang et al., 2002). Because nutrient levels vary among different types of soil, then so does the diversity and numbers of indigenous ambient soil microbes. Separate studies cited by Jiang et al. found that the number of STEC increased by approximately 1.5 – 2 logs CFU/g during the first two weeks of manure incorporation, but then declined significantly greater in loamy sand soil than it did in silty clay loam soil (Lau and Ingham (2001) as summarized by Jiang and Shepherd, 2009).

Table 3.3-5. Survival of STEC in manure-amended autoclaved or unautoclaved soil held at different temperatures

Days of survival at storage temperature (0° C) of:				
	Sample	5	15	21
Manure: autoclaved soil	1:10	77*	138	103
	1:25	63	>226	231
	1:50	70	>226	231
	1:100	35	>226	193
Manure: unautoclaved soil	1:10	42	34	103
	1:25	42	152	193
	1:50	56	109	174
	1:100	49	109	131

*Maximum day at which E. coli O157:H7 was detected by either direct plating or enrichment culture methods. (Jiang et. al., 2002)

The Rhizosphere

The rhizosphere is the environment surrounding the root of a plant. The rhizosphere is a complex miniature ecosystem where there are interactions among soil, roots, and microbes. The rhizosphere is rich in organic compounds released by plant roots and also by microorganisms. These organic compounds may affect the survival and growth of enteric bacteria when those microbes are introduced from agricultural water, manure, or other sources. According to Jiang and Shepherd (2009), studies (by Gagliardi and Karns, 2002) have shown that STEC was able to survive for 25 to 47 days in fallow soil, 47 to 96 days in rye roots, and 92 days in alfalfa roots. This demonstrates the enhancing effect provided by the rhizosphere for pathogen survival. They concluded that persistence of enteric pathogens in the rhizosphere is due to interaction among pathogens, ambient soil microorganisms, the soil conditions, and plant roots (Jiang and Shepherd, 2009).

Scientists also found that the amount of spinach contaminated with generic *E. coli* increased if time since planting of spinach was greater than 66 days (Park et al., 2013). These same scientists concluded that the results suggest that the first cut of spinach crop may be considered less likely to be contaminated than later harvests from the same stand, due to the complex interactions in the rhizosphere.

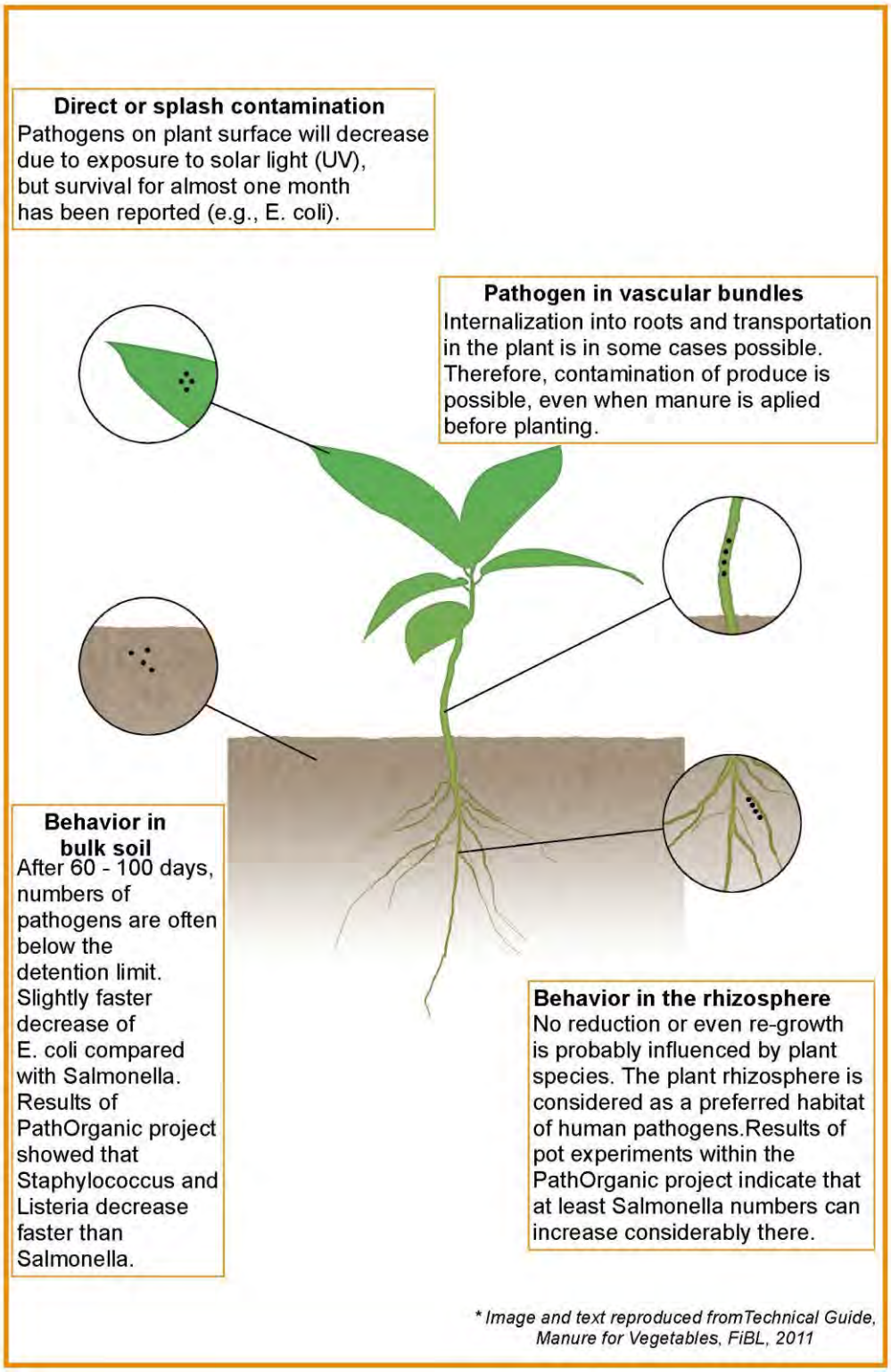
Pathogen, Soil and Plant Interaction

Numerous studies have shown that pathogens can survive on plants and in the soil. When heavy rain or water-gun irrigation occurs, pathogens from the soil surface can be splashed onto the leaves. Pathogens can also be internalized from roots and other openings of the plants, imbedding into plant tissues, and adhering to the roots via soil particles. Growing evidence has demonstrated that enteric and pathogenic bacteria have the ability to colonize plant tissues. Application of raw manure, compost, or irrigation water containing enteric pathogens increases the likelihood of enteric pathogens to inhabit the rhizosphere of plants in the field and to contaminate produce plants. The exact extent to which this pathogen survival proposes a risk has not been established. Figure 3.3-7 summarizes these interactions and qualitative observations. However, studies have established that soil temperature, soil microbial activity, presence of a rhizosphere, types of animal waste, as well as the rate and methods of manure application, all affected the length of time pathogens persisted.

Manure Application Rates and Pathogens

It has been established that competition from indigenous microflora inhibits the survival of manure-borne pathogens (Jiang and Shepherd, 2009). Studies conducted by Lazarovits (2001) demonstrated that organic manure application to soil increased the overall populations of soil microorganisms by up to 1,000 fold (3 logs) and in turn reduced populations of plant pathogens. The intensive application of manure to soil (e.g., one part manure to ten parts soil vs. lesser ratios of manure such as 1:25, 1:50, or 1:100) generally results in greater inactivation of STEC at both 15 and 21°C (when native microflora are active), but not that much at 5°C (Jiang et al., 2002). Jiang and Shepherd further summarized that the application methods used for animal wastes can affect the persistence of manure-borne pathogens. Hutchison et al. (2004) have shown that the populations of *Salmonella*, *L. monocytogenes*, *Campylobacter,* and STEC declined significantly slower in samples with animal waste incorporated into the soil immediately than the populations in samples with the waste left unincorporated on the soil surface. In contrast, another study reported that *Salmonella* survival was significantly longer when hog slurry was surface-spread as compared with results from injected manure (Holley et al., 2006). Results from Gagliardi and Karns (2000) indicated that STEC can travel below the top layers of soil for more than two months after manure application, regardless of disturbed (tilled) or intact (untilled) soil core. These scientific studies concluded that, considering the extended survival of pathogens in manure-amended soil, untreated manure should not be land-applied without adequate treatments to significantly reduce the bacterial populations.

Figure 3.3-7. Soil, plant, and human pathogen interactions



Pathogen Persistence in Manure-Amended Soil

Because there is a slow decline of pathogen populations in manure-amended soil, reducing initial bacterial load is a key factor to reducing the length of pathogen persistence (Jiang and Shepherd, 2009). Fenlon et al. (2000) applied cattle slurry inoculated with minimal amounts of bacteria (e.g., 30 CFU STEC /100 ml) to arable grass plots on a clay loam soil. They could detect STEC only in both the soil and on the grass during the first week after application. In contrast, STEC with very high application rates survived for at least 130 days on manure-amended soil with a grass cover at 18° C (Maule, 1999). Under field conditions, STEC, *Salmonella*, and *Campylobacter* persisted for up to one month, and *L. monocytogenes* for more than one month in both sandy arable and clay loam grassland soil fertilized with livestock manure. Survival times for *Salmonella* were up to ten months (300 days) in soils spread with cattle slurry and eight months (259 days) for soils amended with animal feces (Jones, 1986).

3.3.3.3 Pathogen Delivery to Soils (influence of agriculture)

Manure is a major source of nutrients as well as amendment for improving soil health. The application of manure to farm fields is varied and depends on local conditions and the type of manure that is available. Most of the recommended application methods have been established with the objective of preventing loss of nutrients through volatilization, runoff and leaching and potential pollution of surface and groundwater. Factors that can influence the persistence and survival during the implementation of manure as a fertilizer is the application rate and the manure pathogen load as previously discussed.

Field Application Methods

Manure application guidance provided across the country through extension offices includes minimizing nutrient loss and implementing pollution prevention measures (University of Illinois Extension, 2014a).[9] There are several such guidance steps to take, but a few examples of measures that help to minimize nutrient loss and promote pollution prevention include:

- Use plow-down or disking methods to incorporate manure, otherwise manure left to sit on the soil surface poses the greatest risk of nutrient losses through volatilization and surface runoff.
- Avoid oversaturating soils when applying livestock manure through an irrigation system because the soils may not be permeable enough to absorb the liquids quickly and thus, runoff may occur.
- Knifing manure into the soil is the best way to prevent nutrient loss and protect surface water, and it is the preferred method to incorporate manure in conservation tillage systems because it offers minimal disturbance of crop residue.
- Drag-hose injection eliminates the need to transport manure to the field in a tank, and injecting manure reduces the risk of runoff and odors.

[9] More information may be found at: http://www.thisland.illinois.edu/60ways/60ways_38.html.

USDA organic regulations stipulate that the use of manure for soil fertility must not contribute to the contamination of crops, soils, or water (7 CFR § 205.203(c)). In practice, this may equate to applying manure and considering timing (e.g., time of year such that the farmer avoids application on frozen soil), placement (e.g., avoiding application near waterways), and methods (e.g., injection or immediate incorporation).

State-specific Manure Application Guidance

Review of guidance material from around the country showed a consistent recognition of the value of manure as a nutrient resource and the need for strict requirements for handling, specifically for raw manure. Most states recommend proper and thorough composting of manure, incorporation into soil prior to planting and avoidance of top dressing of plants (WCFS, 2014). A summary listing of these resources is provided in Table C-1, in Appendix C. It is noted that fresh manure is the highest pathogen risk, followed by age/stacked manure and correctly composted manure has the lowest risk. The key components of the state guidance include:

- Plan Before Planting
    - Store manure away from areas where fresh produce is grown and handled.
    - If not composted, age manure.
    - Store manure slurry for at least 60 days in summer and 90 days in winter.
    - Actively compost.
- Plan Manure Application Timing Carefully
    - Apply manure in the fall.
    - Avoid harvesting vegetables or fruits until 120 days after manure application (some states recommend 90 days).
    - If the 120-day waiting period is not feasible, apply only properly composted manure (eXtension, 2013).

The acknowledgement of guidance provided by the states that correctly composted manure has the lowest risk of pathogen contamination compared to raw manure as well as decreased nutrient loss and environmental pollution is consistent with the FDA's position that properly composted manure is an effective and safe fertilizer.

Additionally, many states have restrictive nutrient management programs that regulate how much livestock and poultry manure can be applied to fields annually. These programs require that producers consider the development of composting programs, which have been noted to decrease cost and increase beneficial effects, such as increased uniform germination and decreased weed pressure (MidwestBioSystems, 2012). This is already having an impact on how producers handle manure. Understanding the components that should be integrated into existing programs such as Manure Management Planner (MMP), which currently supports 34 states by generating fertilizer recommendations and estimating manure nitrogen availability based on each state's extension and/or NRCS guidelines, and the mechanisms for integration will potentially allow producers to adapt to consideration of pathogen loads in the same manner in which consideration is given to nutrient loading.

3.3.3.4 Assessment of Existing Soil Health (national and regional conditions)

The ability to influence soil health is dependent on having an understanding of how the soil is designed to function and managing it accordingly. The following planning principles have been identified to achieve the goal of the most favorable habitat possible for the soil food web (USDA NRCS, 2013a):

- Minimize disturbance of the soil.
- Maximize diversity of plants in rotation/cover crops to add diversity to soil microorganisms.
- Keep living roots in the soil as much as possible.
- Keep the soil covered at all times with plants and plant residues.

Figures 3.3-8 to 3.3-11 are presented as the best available information to provide a view of existing soil quality, manure production and use of manure as compared with commercial fertilizer. The data was developed for priority cropland acres and as shown some areas of vegetable production were not captured by this data set. However, trends within the regions may be observed. The soil quality degradation indicator was determined on the basis of the 30-year change in the soil organic carbon (SOC) indicator and the indicator score for the last year of the simulation. The 30-year change in the SOC indicator was calculated as the difference between the SOC indicator score for the first year and the SOC indicator score for the last year in the 30-year simulation. The priority cropland acres with highest potential for soil quality degradation (values that are less than 0) are in the southern regions and California in the west, which are associated with medium and fine textured soil types that are susceptible to erosion.

As stated previously the use of manure is a method of enhancing soil quality and Figure 3.3-8 shows the production of livestock manure across the continental U.S. The amount of raw manure utilized on vegetable producing areas could not be determined from the information available. However, it may be inferred that producers are utilizing manure generated within close proximity to production areas. For example, the West region has high correlation of vegetable producing acres and livestock manure production.

Figures 3.3-10 and 3.3-11 (several pages hereafter) show the percentage of nitrogen application utilizing manure-derived nitrogen (or manure nitrogen) and commercial nitrogen. As previously noted, the dataset considered priority croplands and did not capture all covered produce areas. However, review of the maps show a correlation between manure nitrogen production and manure nitrogen usage associated with the location of covered produce. The locations with the highest manure production and manure nitrogen usage include California, Arizona, Washington and Oregon in the west; southern part of Texas, coastal areas of the southeast and the upper Midwest. The application rate in these areas ranged from 75 to over 125 lbs/acre. Conversely, commercial nitrogen application rates were lower in these areas with rates of 1 to 25 lbs/acre. Based on figure 3.3-9, 2000+ lbs of manure nitrogen is produced per county and with 125+ lbs applied per acre it appears that the manure that is being generated is being utilized and that there is potential capacity to use more considering that one (1) dot of covered produce is equal to 1,000 acres. It should be noted that these locations support many types of agriculture (not just

covered produce), therefore, an exact correlation may not be made between manure nitrogen application and growers of covered produce.

Figure 3.3-8. Priority cropland with highest potential for soil quality degradation

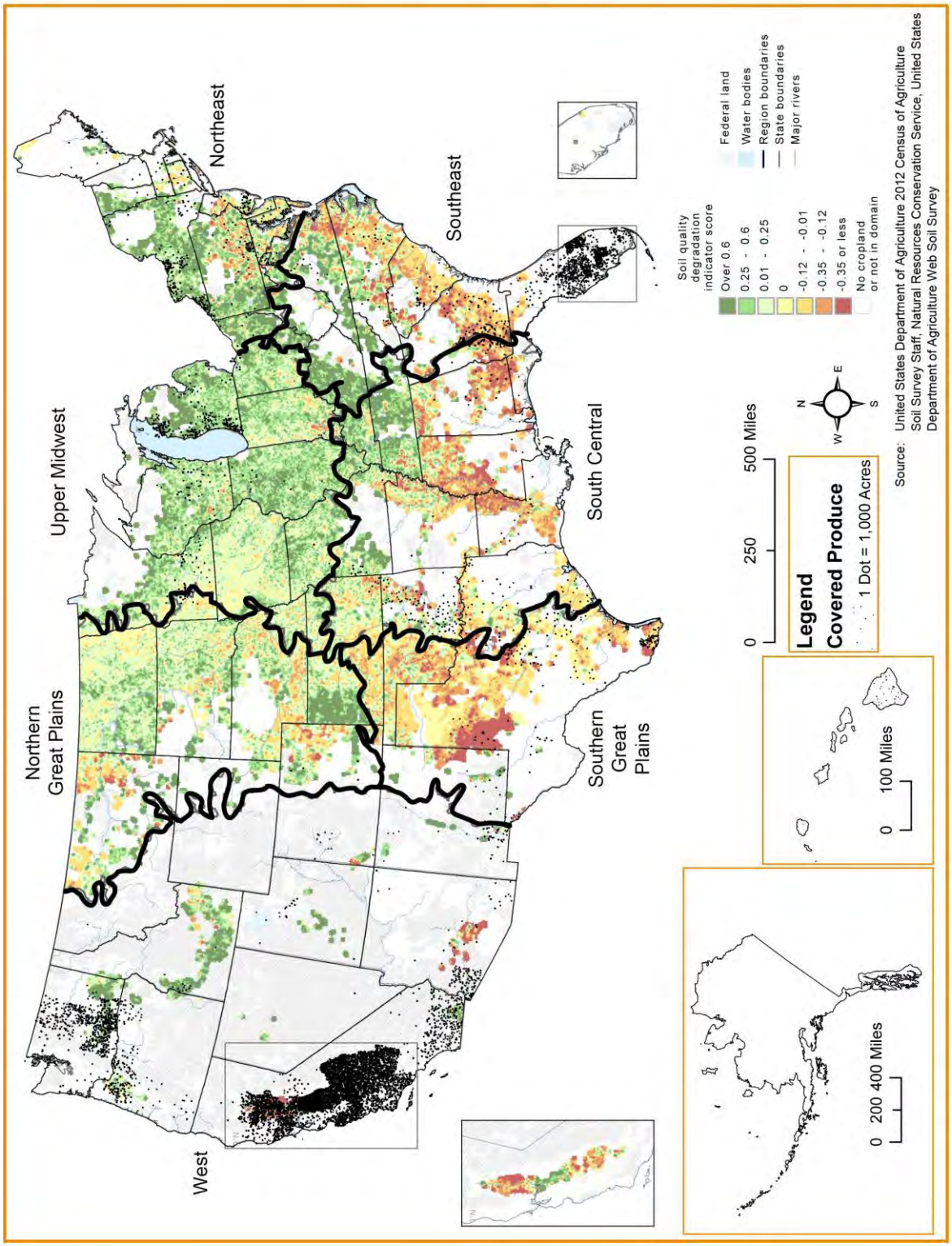


Figure 3.3-9. Estimated manure nitrogen production from confined livestock

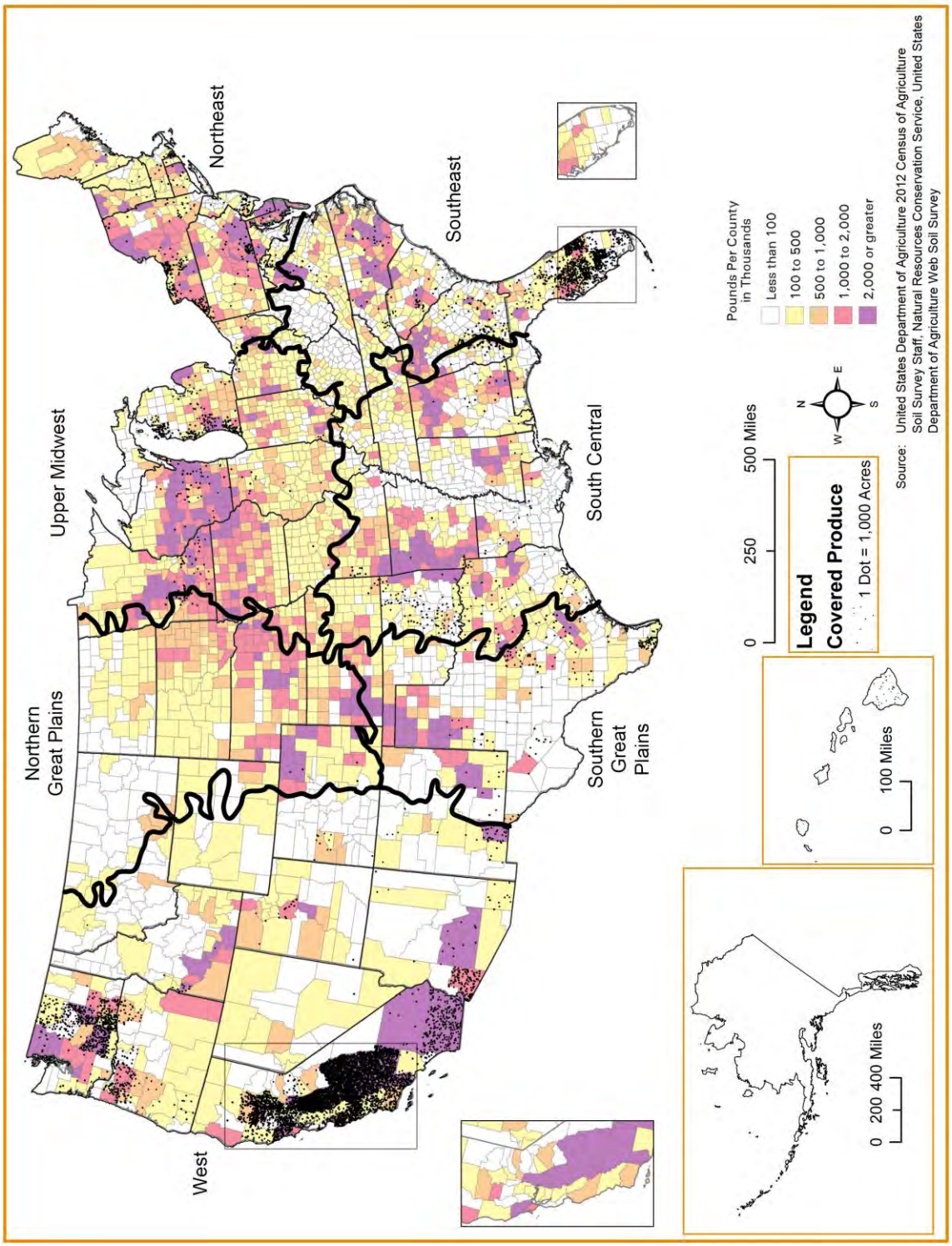


Figure 3.3-10. Average annual commercial nitrogen application rates

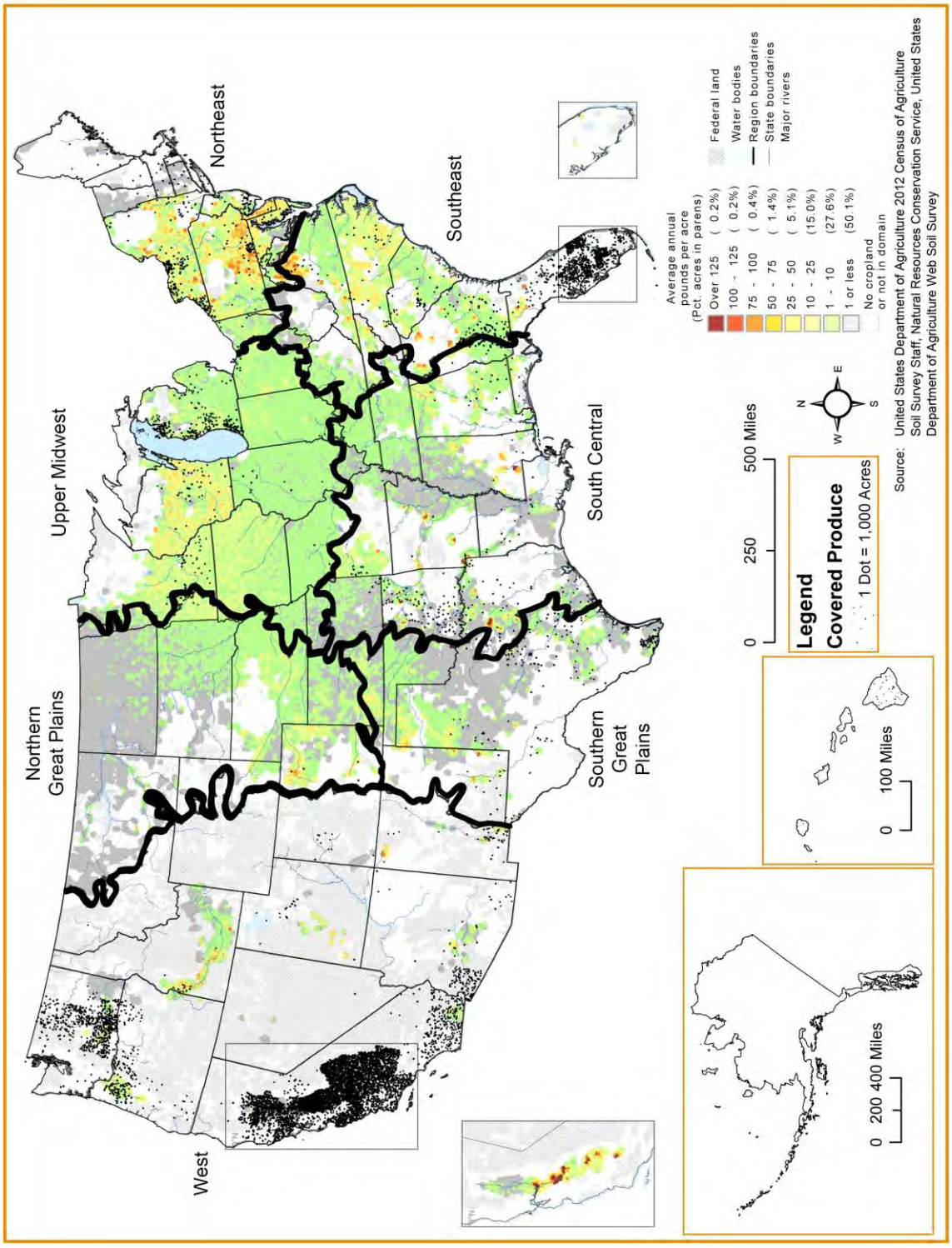
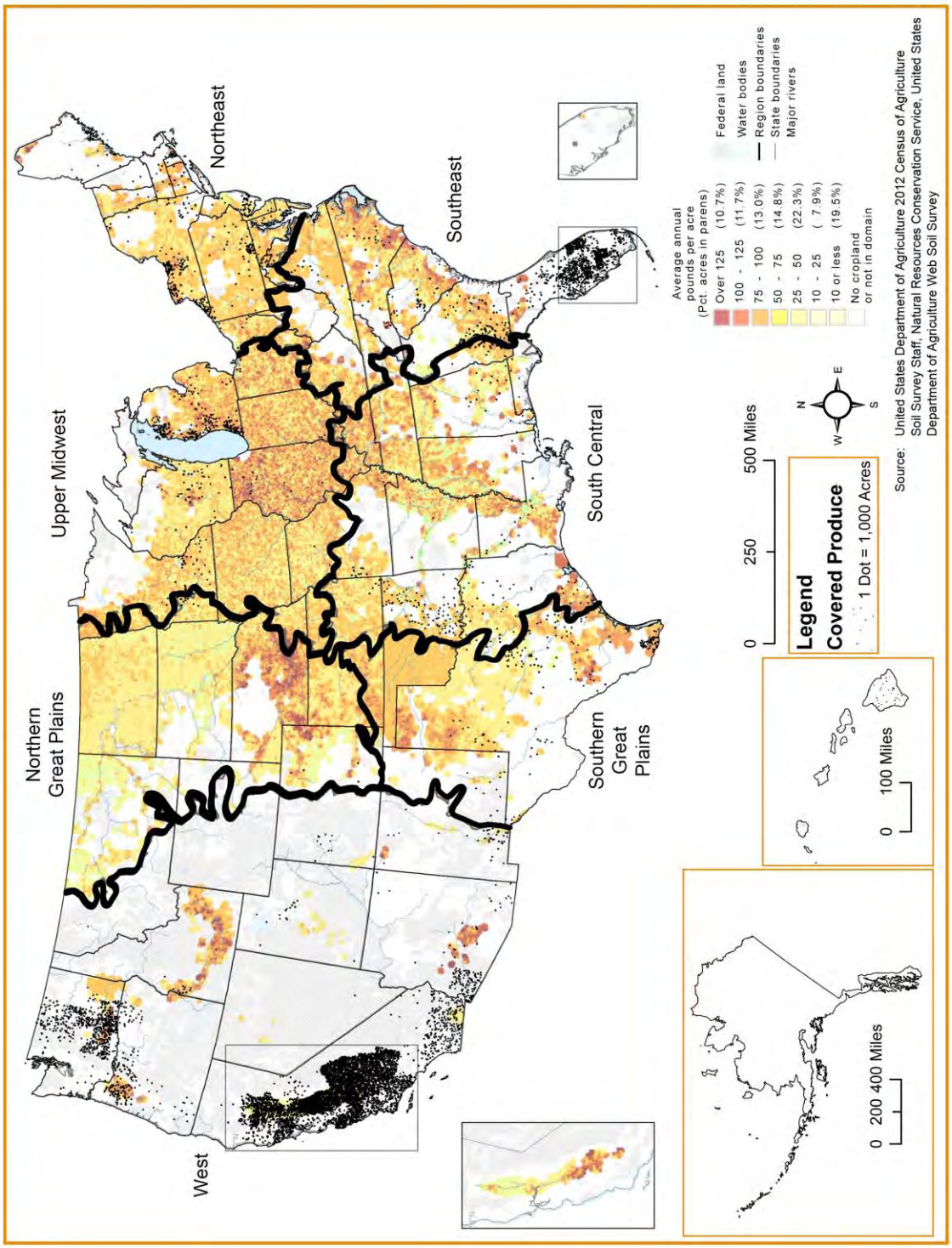


Figure 3.3-11. Average annual manure nitrogen application rate

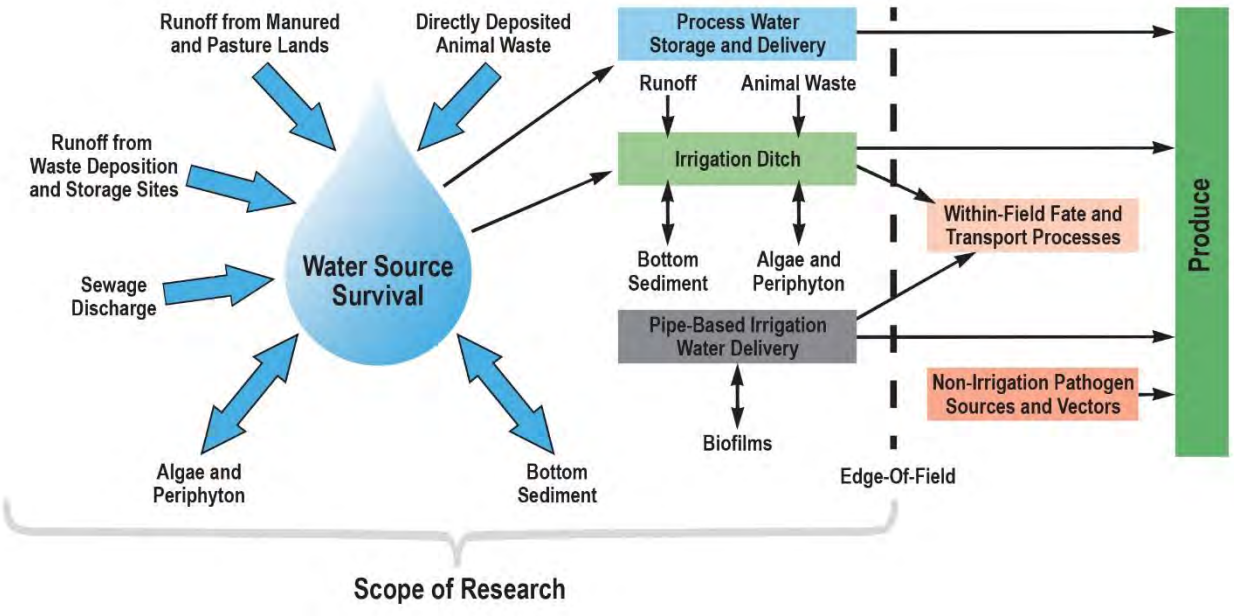


The previous two Figures (3.3-10 and 3.3-11) show that less than 2 percent of priority croplands applied more than 50 lbs. of manure nitrogen/acre annually compared with more than 50 percent of priority croplands annually applying more than 50 lbs. of commercial nitrogen/acre. While a direct correlation cannot be determine from these data, the data suggest that priority cropland is still significantly utilizing commercial fertilizer, and therefore, manure for use on covered produce is readily available.

3.3.3.5 Soil and Agricultural Water (influence of agriculture)

The presence of pathogenic microorganisms in irrigation waters is considered to be a potentially important factor in the pre-harvest contamination of fresh produce. Figure 3.3-12 demonstrates that pathogens will migrate with water and may be transported via overland flow, infiltrate into the soil followed by through flow, or drainage through soil. The partitioning of water at the soil surface is controlled by the rate of application of water or effluent vs. the soil's infiltration rate. Most infiltrating water is filtered and the microorganisms are trapped in pore throats that restrict passage (straining) and filtration and attachment to solid surfaces (adhesion). These processes which are controlled by soil physical properties such as texture can affect the survival of microorganisms in soil. For instance, it has been documented that straining has a weak effect in sandy soils due to the presence of pore spaces (Buchan and Flury, 2004). While many of the essential pathogen transport processes associated with irrigation are currently not well understood or modeled it is established that irrigation water is a method in which pathogens enter the soil. The following flowchart demonstrates areas of current research to increase understanding of these processes (Pachepsky et al., 2006).

Figure 3.3-12. Pathogenic transport and survival within overland flow (agricultural water)



Source: Pachepsky et al. (2011)

Soil and Irrigation Methods

There are four primary types of irrigation methods (surface, sprinkler, drip or trickle and subsurface). Soil properties or characteristics (e.g., soil texture, and slope) along with environmental conditions (e.g., climate including precipitation, water quality and availability) have an impact on the choice of irrigation method that the farmer decides to use. For example, sandy soils allow water to transport through more quickly (i.e., low water storage capacity and high infiltration rate); therefore, these soils require more frequent irrigation water applications. Under these circumstances, sprinkler or drip irrigation are more suitable than surface irrigation. For loam or clay soils all four irrigation methods are suitable, but surface irrigation is what is most commonly used. Clay soils (these are soils that have low infiltration rates) are ideally suited for surface irrigation methods. When a variety of different soil types is found within one area, sprinkler or drip irrigation is what is most commonly used, as it ensures a more even water distribution.

Surface irrigation is used across the country for all types of crops. Sprinkler and drip irrigation, because of their high relative costs (initial capital costs) are mostly used for high value cash crops, such as for certain types of produce and fruit trees. Drip irrigation is more often employed to irrigate individual plants or row crops such as some vegetables and sugarcane.

Furrow irrigation is often suitable for a wide variety of soils and crops, but especially it is used for row crops. (Brouwer et al., 1989)

Drip Irrigation for Vegetable Crop Production

There are two fundamentally different drip irrigation systems for vegetable crop production:

- Temporary surface system that are installed after crop establishment and removed before harvest; and
- Semi-permanent, buried systems that are left in place for multiple crops.

Appropriate fertility management may be profoundly different with the two systems. With a temporary surface system, phosphorus application is typically done before system installation. The wetting is from the top down, pushing soluble nutrients toward the root zone. Because the system is temporary, and conventional tillage is practiced between crops, there is no significant ‘mining’ of nutrients from a particular region of the soil profile, nor are the effects of maintenance chemicals (acids, for example) spatially concentrated. By contrast, with a semi-permanent, buried system the surface 4-6 inches of soil may (depending on soil characteristics and system depth) often be too dry for active nutrient uptake (Hartz, 2004). Evaporation from the soil surface may move soluble nutrients into this dry zone, beyond the reach of the crop. Since successive crops will draw the bulk of their nutrients from a confined area in the soil, the nutrient status of that area may change substantially over time. Acid-based products applied through the drip system can change pH of the wetted area, potentially affecting micronutrient availability (Hartz, 2004).

More efficient irrigation will reduce nitrogen leaching loss, but growers do not always achieve improved efficiency with drip irrigation. Another reason why drip irrigation may increase nitrogen fertilizer requirements is that the limited wetted zone reduces the amount of nitrogen mineralization from SOM. This is an issue primarily with buried systems, because most nitrogen mineralization occurs in the tillage zone, which may remain dry during much of the season. Tillage practices that confine crop residues to the surface few inches of soil, and irrigating a crop with the drip instead of sprinklers, will minimize the availability of nitrogen in those residues. Lastly, with buried systems, evaporation from the soil surface over time can deposit a considerable quantity of NO_3-N (nitrogen derived from the nitrate ion) in the dry surface soil. While this nitrogen may be recovered by a subsequent crop, it may be largely beyond the reach of the current crop (Hartz, 2004).

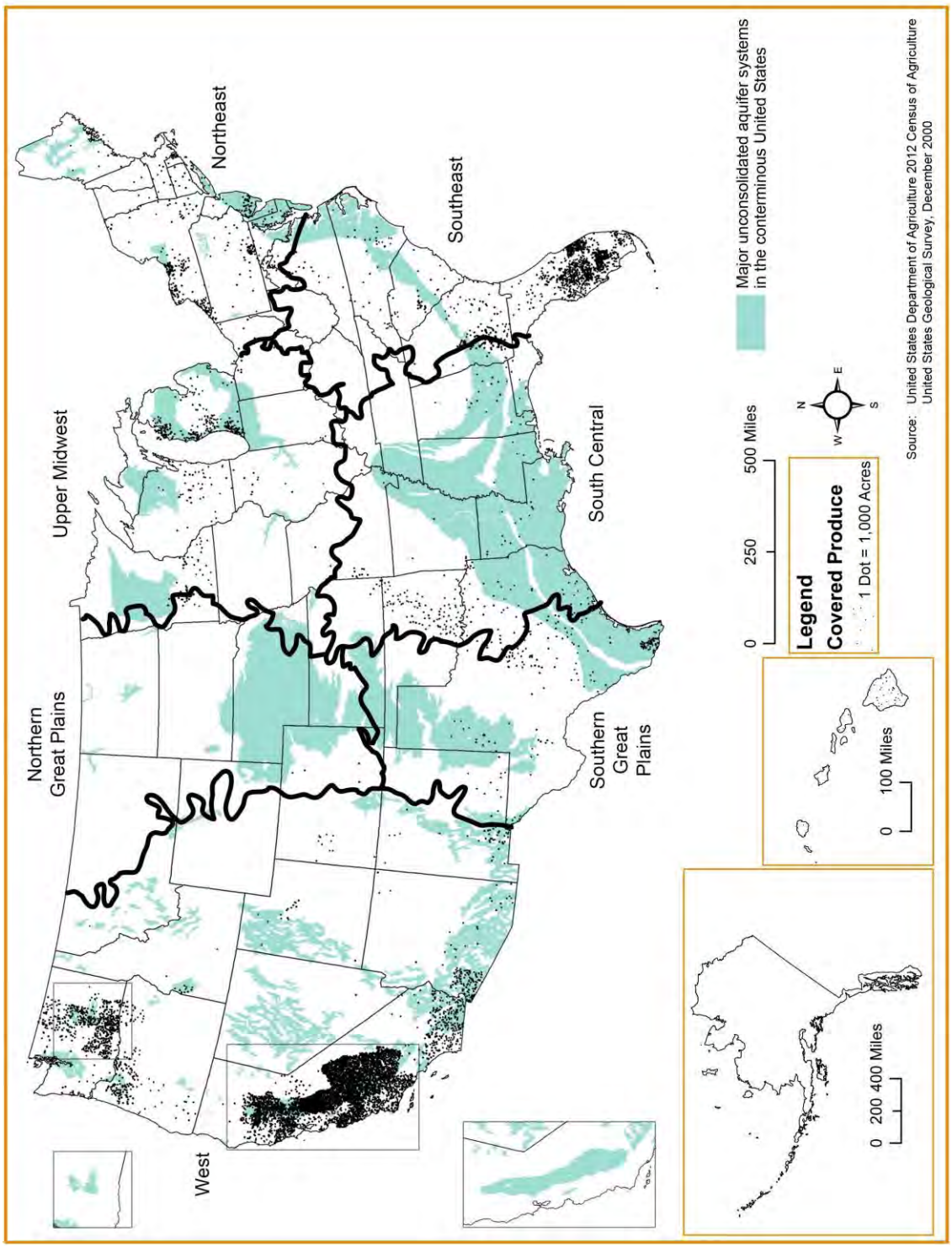
Figure 3.3-13. Example of soil subsidence as a result of aquifer compaction (Photo credit: Dick Ireland, USGS)

Soil and Groundwater Pumpage

According to USGS, more than 80 percent of the identified subsidence in the nation is a consequence of underground water exploitation, and factors such as increasing residential and commercial development, and continued drawdown of water resources threatens to exacerbate existing land-subsidence problems and initiate new ones. In many areas of the arid Southwest and in more humid areas underlain by soluble rocks such as limestone, gypsum, or salt, land subsidence is an often overlooked environmental consequence of our land- and water-use practices. Figure 3.3-13 is a picture of the San Joaquin Valley Southwest of Mendota in the agricultural area of California (USGS, 2000). Pumping of groundwater for irrigation has caused the land to drop. The past surface elevation is shown by the years on the signs.

Figure 3.3-14 (USGS, 2000) shows the extent of compaction of aquifer systems throughout the U.S. caused by groundwater withdrawals. As the groundwater is pumped out, the aquifer becomes stressed and the soils around it consolidate, which is non-reversible. Thus, the total volume of the silts and clays is reduced, resulting in the lowering of the soil surface. The damage at the surface is much greater if there is differential settlement, or large-scale features, such as sinkholes.

Figure 3.3-14. Areas of subsidence attributed to compaction of aquifer systems



Soil and Chemically Treated Agricultural Water

Chlorine chemicals are very effective against bacteria, viruses and fungi that contaminate water. Four types of chlorine chemicals are commonly used in agriculture: sodium hypochlorite, calcium hypochlorite, gaseous chlorine and chlorine dioxide. Chloride is not adsorbed or held back by soils, and so chlorine compounds move readily with the soil-water and may be taken up by the crop where it accumulates in the leaves (FAO, 1994).

Two of the more popular treatments, though still a very limited practice across the U.S., are injection of calcium hypochlorite or chlorine dioxide (e.g., such as for anti-fouling of distribution infrastructure). For irrigation of many key crops, the volumes of water being pumped for overhead irrigation, for example, may be in excess of 1,500 gallons per minute. In California and Arizona farms where this is being applied, water quality is generally good and the disinfectant demand is low. Therefore, low doses, 2-5 mg/L (2- 5 parts per million (ppm)) of active ingredient are sufficient. Lower doses of these chemical treatments reduce potential detrimental effects on the crop; however, the concern remains for chronic effects of large-scale use over long periods of time as soil quality may be degraded.[10] Such a result may further also have adverse impacts on wildlife and habitats. In water and soil, sodium and calcium hypochlorite 217 separate into sodium, calcium, hypochlorite ions, and hypochlorous acid molecules. Calcium hypochlorite 218 and sodium hypochlorite are not bioaccumulative (USDA AMS, 2011).

3.3.3.6 Factors Influencing Soil Health (soil amendments)

Most agricultural lands poorly serve adjacent ecosystems due to the high degree of disturbance, low diversity and high human inputs (e.g., nutrients, pesticides, etc.); therefore, the adjacent ecosystems tend to be of poorer quality. This is evident by comparing forest soil organic matter (SOM) at 4.3 percent while cropland SOM is now 1.6 percent. Nationally more than 50 percent of SOM has been lost in the past 100 years, most since the 1950's (USDA NRCS, 2013a), methods to build and maintain SOM are critical to soil health.

In addition to plant nutrients (N, P, and K), animal manures work to build soil organic matter and improve soil structure. Better soil structure helps to improve water holding capacity, aeration, and aggregation, and thus drainage and time windows for workability are improved. In addition, many trace nutrients needed for optimum plant growth are available from manures, which may not be present in commercial fertilizers. When applying animal manure, nutrients are released more slowly and over a longer period of time as compared to most commercial fertilizers (Rowell and Hadad, 2014) as demonstrated in Figure 3-3.15. However, if manure is applied to fields in excess the result is a high phosphorus level that discourages plants to develop a healthy mycorrhizal fungi relationship, which then limits the plant's potential to achieve other benefits, such as water and other nutrient exchange. Where there is an overabundance of manure production on a farm, such that the volume of manure that is produced is greater than the farm's potential to "assimilate" the manure's nutrients, there is a potential to create a water quality

[10] It should be noted that negative ions associated with chlorine, for example, would leach out of the soil readily and calcium and sodium ions would be less readily transported out of the soil media.

problem, unless the excess manure is transported to another growing area where it can be properly applied (Gollehon et al., 2001).[11] An example of when manure may be applied in excess may include when livestock operations do not have sufficient crop production acreage on which to spread manure at agronomic rates. In other words, too much manure may be spread on too few acres to make it efficient for proper plant/crop nutrient uptake. Manure will generally have more nitrogen than phosphorus, but in proportion to crop uptake, manure is generally nitrogen limited, especially with longer storage or treatment. Nitrogen and phosphorus interaction in the environment is important to consider. Nitrogen is more easily soluble in water than is phosphorus, and is not held by the soil's cation exchange capacity when nitrate (anion) forms. Nitrogen is thus more easily transported with water, especially via leaching, but also via runoff. Nitrogen is also lost to the air via denitrification and volatilization. Phosphorus can be leached in certain circumstances (e.g., heavily phosphorus-loaded soils with macropore flow, more frequent in tile drained systems), and it can also be mobilized with erodible soils via runoff. Both nitrogen and phosphorus are known to create water quality problems in receiving waters including causing an increase in algal production (as well as overproduction in vascular plants) (Gollehon et al., 2001; EPA, 1998). The acceleration of algal production and vascular plant biomass in receiving waters due to excess nitrogen and phosphorus coupled with decomposing organisms in the water will often result in an increase in demand for oxygen, which then depletes the dissolved oxygen in the waterbody. The effect may be fish kills (and death of other aquatic animals), and in some cases harmful algal blooms can endanger human health (EPA, 2012a). This particular process of water quality degradation is called eutrophication. Eutrophication and other water quality problems resulting from excess nitrogen and phosphorus from agriculture can be managed through proper nutrient management planning (see Chapter 3.4.3).

Manure can also contain toxic compounds, which depends upon the food supplements that the cattle or poultry may be fed, and in turn concentrates in the manure. These toxic compounds may also accumulate in the soil where manure is applied (USDA NRCS, 2013a; Brady and Weil, 2002; Magdoff and van Es, 2009).

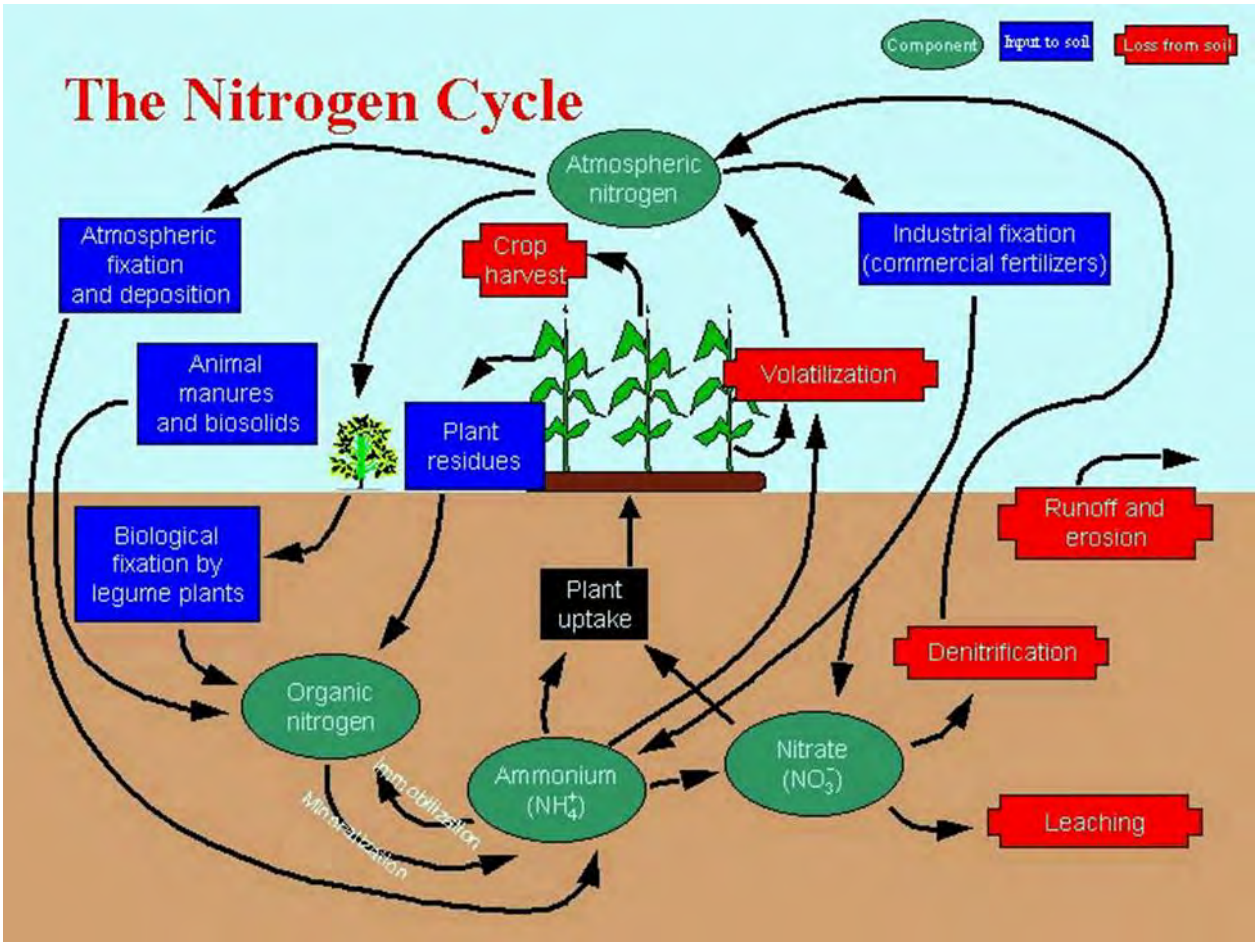
The use of commercial fertilizers has significantly increased crop yields; however, it has been determined that it has a detrimental effect to the healthy functioning of soil. Specifically the impact of fertilizer has shown the following effects (USDA NRCS, 2013a; Brady and Weil, 2002; Magdoff and van Es, 2009):

- Short-circuits rhizosphere processes. The rhizosphere is the area adjacent to the root that has the most biological activity taking place such as mineralization (nutrient release) and disease prevention. Excessive fertilizer discourages this area from developing to its full potential. Excessive manure can also result in excessive nutrient availability leading to a degradation in the mycorrhizal fungi relationship, resulting in impacts to the plant's ability to conduct adequate water and nutrient exchange, and ultimately causes damage to the plant/crop.

[11] The foremost cause of water quality degradation in the U.S. is from excess loading of nitrogen and phosphorus into waterbodies.

- The presence of excessive mineral nitrogen depresses nitrogen-fixing bacteria in soil. This effect can occur from either excessive fertilizer or mineral components of manure.
- Poorly timed and excessive mineral nitrogen inputs increase the risk of nitrogen leaching or denitrification.
- Fertilizer nitrogen is applied in one of two forms, NH_4^+ or nitrate, both are inorganic and very water soluble, which can leach or leave the field through surface runoff, and field tile.
- Nitrogen inputs allow for bacterial decomposition of high-carbon SOM.
    - Although still widely debated by scientists in the field, it has been suggested that the Morrow plots in Illinois show that addition of nitrogen has led to the loss of 50 percent of the SOM since they began using it in the plot in the 1950s.
    - Loss of SOM has been accomplished by stimulating the bacteria throughout the soil profile to decompose organic matter, without balancing carbon losses with adequate inputs of additional carbon via, for example, manures or cover crops.
- Synthetic fertilizers are salts, which can lead to osmotic shock in plant roots if over applied. We would note that manures also contain quite a bit of salt due to feed formulations.

Figure 3.3-15. Transport of organic nitrogen (manure) and inorganic nitrogen (fertilizer) (Image credit: the Potash and Phosphate Institute)



Raw Manure and Composted Manure

A prime interest with organic amendments is whether or not to compost the manure prior to application. Composting changes both the physical and chemical structure of manure, which has both positive and negative results. Physical changes that occur during composting include: decreased water content, decreased dry matter, decreased volume and increased bulk density. These changes are generally considered advantageous, because smaller mass/volumes are much easier to transport and apply. Composting manure may also serve to eliminate pathogens, parasites, weed seeds and odors, and it has been found to increase disease suppression effects. Composted cattle manure has proven as effective as raw manure in promoting crop yields. However, composting may increase nutrient losses. Manure nitrogen is lost during the composting process through ammonia volatilization, denitrification and leaching, and additionally, much of the plant available nitrogen is immobilized in organic forms. Due to nitrification, compost may contain higher NO_3^- and lower NH_4^+ concentrations than fresh manure. Overall inorganic nitrogen availability, however, is often less in compost than fresh

manure and composting may benefit the environment because organic nutrients are less likely to run off to surface waters or to leach to groundwater (Michigan State University Extension, 2012).

Green Manure

"Green manuring" involves the soil incorporation of any field or forage crop while green or soon after flowering, for the purpose of soil improvement and benefits the soil in many ways (Sullivan, 2003). These benefits include the addition of organic matter and improvement to soil structure, it has been reported that "the contribution of organic matter to the soil from a green manure crop is comparable to the addition of nine to 13 tons per acre of farmyard manure or 1.8 to 2.2 tons dry matter per acre" (Sullivan, 2003). The nitrogen fixation capacity of legume cover crops produces from 40 to 200 lbs. of nitrogen per acre and also crops help recycle other nutrients (P, K, Ca, Mg and S etc.) accumulated by cover crops during a growing season (Sullivan, 2003). Aeration of soil is achieved from extensive rooting action of some cover crops and supports weed suppression. One limitation of cover crops is water consumption especially in areas with less than 30 inches of precipitation per year but the use of native legumes that are adapted to drier conditions can mitigate some of the water needs (Sullivan, 2003). It is also noted that many vegetable rotations can accommodate cover crops. For example, in some regions, buckwheat can follow lettuce and still be tilled down in time for fall broccoli. Hairy vetch can work well with tomatoes and other warm-season vegetables. The vetch can be killed by flail mowing and tomato sets planted into the mulch (Sullivan, 2003).

3.3.3.7 Soil and Grazing (domesticated and wild animals)

Livestock grazing can considerably affect the structure, composition, fertility, chemistry and function of soil in ways that either improve or compromise both short and long-term productivity. Grazing, depending on how it is managed, can change soil structure, and can increase soil compaction. Compaction reduces water and air infiltration into the soil and increases runoff. Grazing can increase the organic matter decomposition rate, alter the amount of various nutrients stored in soil, and lower pH if not managed. Grazing increases short-term soil nutrient availability (Roberson, 1996).

3.3.3.8 Soil and Effect of Farm Size

The capacity of the soil to function is not dependent on the size of the farm. The exclusion of farms to be exempted by the PS PR constitutes a very small portion of the total farmed acreage of the United States. Therefore, the vast majority of soil resources will continue to receive the existing management practices.

3.4 Waste Generation, Disposal, and Resource Use

3.4.1 Definition of the resource

With respect to this EIS, waste generation primarily means the animal waste, or excreta (an example of a BSAs of animal origin), that is created during the practices of livestock and poultry production (and animal products) and that is used to amend soil nutrient content in order to promote plant production and increase crop yields. For the purposes of this EIS, the resource also includes processed human waste, which is rarely used for soil amendments, and must be used in accordance with EPA regulations (found in 40 CFR Part 503 Subpart D).

Disposal and resource use means how the resource is applied to crops in raw form (untreated) or composted (treated) or processed (chemically or thermally pasteurized), or how it is otherwise stored prior to use.

In terms of identifying the baseline conditions of the resource, this section identifies the following factors:

- Regulatory or industry practices that govern the use or disposal of the resource;
- How the resource is applied to crops (current baseline conditions);
- Domesticated animal considerations;
- Application to harvest intervals for produce covered by the PS PR; and,
- Transportation related considerations.

3.4.2 Regulatory Oversight

Animal Waste

The USDA organic program is a nationwide program for certified organic producers, including fresh produce. For those certified farms that participate in the USDA organic program, the untreated resource (raw manure) must be applied in accordance with organic regulations (7 CFR 205.203(c)(1) and (2)). These regulations also prescribe application to harvest intervals for raw manure on fields where crops are grown, and they specify methods for composting raw manure in order to treat the resource. Specifically, USDA requires that "[t]he producer [participating in the USDA organic program] ... manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances." (7 CFR 205.203(c)) A comprehensive risk assessment was not conducted by USDA when it established the organic regulations with respect to the safety of applying raw manure to human food crops. The preamble to the organic regulations states, "Should additional research or federal regulation regarding food safety requirements for applying raw manure emerge, [Agricultural Marketing Service] will ensure that organic production practice standards are revised to reflect the most up-to-date food safety standard." (65 Fed. Reg. 80548, 80567)

State governments in a majority of states (45 states with the exceptions being Alaska, Connecticut, Hawaii, Nevada, and Wyoming) have enacted nutrient management programs that

apply some restrictions on manure disposal (University of Missouri Extension, 2008; WCFS, 2014). A mix of state and local agencies, working in series with USDA conservation districts, oversee individual nutrient management plans for farms (including for CAFOs and farms that grow produce that may be covered by the PS PR). These plans, in part, provide application rates for efficient use of the product. Manure is typically managed to avoid over-application of target nutrients (nitrogen or phosphorus) as part of a CWA strategy (as regulated by EPA). Time-of-year restrictions, application procedures including incorporation and setback distances, and other measures are primarily intended to avoid eutrophication of surface water and contamination of groundwater with limiting factor nutrients.

The USDA GAP/GHP program (see Chapter 2.1) also addresses animal manure as soil amendments in a way that helps to minimize microbial food safety hazards. The GAPs program is based on recommendations made in FDA's Guidance to Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (FDA, 1998). Similar practices are applied under produce marketing agreements, which are also voluntary programs that exist for growers across the nation.

Composting

There are many different methods used for composting materials, which depends on the material composition (animal or human waste, vegetable waste, yard scraps, etc.) in order to effectively break down the parent materials for use in whatever application the compost is meant to be applied. There is no one scientifically approved method of composting organic material. The use or storage of compost and raw manure may be regulated by EPA under the CWA when there is the potential to release pollutants such as nitrogen and phosphorus, organic matter, sediments, pathogens, heavy metals, hormones, antibiotics, and ammonia to the environment (40 CFR §§ 122.42 (e)(1)(ix); (e)(2); and (e)(5), and 40 CFR § 412.4(c)(5)). Facilities that may store raw manure and may perform composting operations (e.g., CAFOs) may be required to apply for a NPDES permit (40 CFR §§ 122.42(e)(1)(i) & (e)(5)). Although not all CAFO operations are required to obtain and hold NPDES permits, those that discharge or propose to discharge must comply with terms of such a permit.

3.4.3 Current Background Conditions

Data Sources

The USDA NASS and ERS have been collecting information on agriculture since the early 20th century, and have been collecting information on the prevalence of BSAs use as a soil amendment for over ten years. USDA conducts its Census of Agriculture survey every five years. The data generated from the survey is publicly available on the USDA Web site, and was used to develop portions of the affected environment for this EIS, specifically data from the 1997, 2002, 2007, and 2012 surveys, where information was available[12].

[12] http://www.nass.usda.gov/Data_and_Statistics/.

Other major sources of data used to establish the affected environment for this resource include the USDA NASS Fruit and Vegetable Agricultural Practices survey (USDA NASS, 2001), and the Fertilizer Use and Price statistics (USDA ERS, 2013b).

General Conditions

Although the resource is defined as animal excreta or BSAs of animal origin, soil amendments can include (alone or in combination) the following three general classes: (1) Non-biological elemental soil amendments (e.g., fertilizer); (2) Non-animal biological organic material (e.g., vegetable compost); and (3) BSAs of animal origin, as detailed below. As a general practice, most farms, including farms that would be covered by the PS PR, use a combination of soil amendments to fertilize crop fields.

The USDA survey taken in 1999 (USDA NASS, 2001) was valuable in gathering statistics on numbers of farms and acreage of both fruit and vegetable growers in major producing states, and to gauge the fruit and vegetable industry's respective relative reliance on various soil amendments. USDA organic regulations became effective in 2002; therefore, this survey would include farms that have since achieved organic certification. The criteria used in selecting the targeted fruits and vegetables in the survey were: 1) produce that are included in the top 20 fresh fruit and vegetables consumed in the U.S.; 2) produce with the greatest number of planted acres in the U.S.; and 3) produce that is predominately consumed uncooked. Below are highlights of the survey[13].

- Organic elemental (Non-Biological) fertilizer use:
  - 15% of Fruit Program state farms applied *organic* elemental fertilizer in 1998-1999 (13% of the acreage).
  - 14% of vegetable farms applied *organic* elemental fertilizer in the same time (6% of acres).

- Biosolids (Chemically or Thermally Processed):
  - 1% of fruit farms surveyed applied biosolids (sludge) in Fruit Program states in 1998-1999 (2% of acres).
  - 1% of vegetable farms surveyed applied biosolids in Vegetable Program states in the same time (1% of acres).

- BSAs of animal origin:
  - 5% of fruit farms surveyed applied manure (BSAs of animal origin) in 1998 (6% of both farms and acreage in 1999):
    - 12% of surveyed fruit farms using BSAs of animal origin applied *composted* (treated) manure (21% of acreage); 66% used *aged or not treated* manure; and 23% used *other manure types or were unsure* of treatment methods.

[13] Note that the survey did not include statistics on fertilizers considered inorganic; or statistics on organic materials like cover crops. Until the 2012 Census of Agriculture, USDA did not collect information on cover crop practices.

        - 65% used dry broadcast without incorporation; 29% used dry broadcast with incorporation; 5% used liquid broadcast without incorporation.
    - 9% of vegetable farms surveyed applied BSAs of animal origin in 1998 (10% of farms, on 3% of acres in 1999):
        - 41% of surveyed vegetable farms applied composted (treated) manure (55% of acreage); 31% used aged or not treated manure; and 12% used other manure types or were unsure of the treatment methods.

The statistical information (percentage of farms using certain amendment) that were gathered as a result of the survey, were used by FDA in calculating the numbers of covered produce farms and their relative acres that apply various BSAs of animal origin, as published in its *Analysis of Economic Impacts: Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (FDA, 2013b).

3.4.3.1 Types of Soil Amendments

1) Non-Biological Elemental Soil Amendments

Non-biological soil amendments can include soil conditioners that help balance pH (relative acidity/alkalinity), provide carbon, and provide macronutrients and micronutrients. Non-biological soil amendments may include:

- Over nineteen pulverized or powdered mineral supplements (e.g. *inter alia*; limestone, dolomite, perlite, vermiculite);
- Humic substances (complex carbon compounds found in soil); or,
- Elemental/chemical fertilizers (defined as a product that contains the major and the secondary macronutrients at measurable levels confirmed by a qualified laboratory).

USDA organic regulations allow certified organic growers to use naturally occurring mineral additives such as soft rock phosphate, sulfate of potash magnesia, sulfate of magnesia, natural organic leonardite (potassium humate), lime/dolomite, and greensand. Specific micronutrients used as soil amendments may also be used by organic growers when soil deficiency is documented by testing (7 CFR §205.601(j)(6)). Other produce growers may add any of these non-biological soil amendments to correct for deficiencies in plant growth needs, detected by soil testing. Elemental/chemical fertilizers are an alternative to the nitrogen, phosphorus, and potassium supplied by manure, and are in fact in widespread use currently in the produce growing industry for balancing crop nutrient needs. Elemental soil amendments can be liquid which is injected, or pellets which are broadcast at planting time or side-dressed during the growing season if necessary for optimal for plant uptake. Although convenient, a major disadvantage of elemental soil amendments can be the variable direct cost of purchasing fertilizer that vary annually, and have increased over time.

Table 3.4-1 below shows a 15-year trend in fertilizer costs adjusted for coverage and corrected for inflation and price indexes. The table demonstrates that costs of fertilizer have increased over this time period; however, use of these fertilizers shows a downward trend over the same time period. This may be attributable to any number of factors including; enrollment in the USDA

organic program; increased use of different farming methods such as use of cover crops or green manure; increased use of hybridized crops that improve yields under changing climate conditions; and/or increased use of nutrient management plans.

Table 3.4-1. Farm production expense for fertilizer, lime, and soil conditioners

Year	1997	2002	2007	2012
$1000x Purchase [a]	9,999,752	9,751,400	18,107,194	28,532,713
% Cost increase/ decrease Trend [a]	--	-0.5%/year	+17.1%/year	+11.5%/year
Fertilizer Price Indexes [a]	121	108	216	336
Any fertilizers or chemical expenses reported in numbers of farms[b]	1,463,256	1,376,395	1,288,360	1,187,446

Sources: [a] USDA ERS, 2013b and
[b] USDA NASS: 2014a, 2009a, 2004 (derived from respective 2012, 2007, and 2002 Censuses)

A 1999 survey of fruit and vegetable farms (USDA NASS, 2001) indicated organic fertilizer use comprised 15 percent of the fruit farms and 14 percent of vegetable farms surveyed in principal production states in the year of the survey. In comparison as stated in Chapter 2.1 of this EIS, approximately 12.5 percent of covered produce growers (4,438 farms of 35,503 covered farms) used BSAs in 2007. Fertilizer use therefore slightly exceeds the overall use of BSAs for meeting production nutrient requirements. Reasons for the slightly higher percentage of produce farms using fertilizers despite their higher costs compared to BSAs may include uniformity and predictability of fertilizer. Another contributing factor may be because of organic marketing or participation on a state marketing agreement that stipulates restrictions on usage of BSAs on specified produce crops.

2) Non-Animal Biological Soil Amendments

These soil amendments include decomposed and fresh varieties.

Decomposed plant compost/mulch/detritus may include leaf mold, spent mushroom mulch (depending on its preparation), peat moss, composted yard-trimmings and pre-consumer vegetable matter (provided those contain no table scraps or animal biological components), seaweed/kelp emulsions (containing no fish), and various grain meals like cotton seed meal.

Fresh vegetation material (not decomposed) may include cover crops and crop residue tilled into the soil, and vegetation mulch (e.g., straw, grass-clippings / landscape trimmings, amended peat moss or sawdust).

Non-animal BSAs are typically applied during the off-season by incorporating the material into the soil by disking and harrowing, or direct addition to the furrows during the sowing/planting activity; or applied as mulch after the plants have emerged. Early addition of these materials is necessary for optimal uptake of nutrients by plants because decomposition must occur to allow the nutrients to be available.

3) BSAs of Animal Origin

For purposes of analysis, there are two classifications of BSAs of animal origin: (1) Untreated and (2) Treated. A common untreated BSA of animal origin is manure from livestock or poultry; and a common treated BSA is effectively composted manure. All BSAs of animal origin are derived from animal excreta or animal by-products that present the opportunity for bacteria and other microbes that can include pathogens. The increasing levels of treatment and processing are intended to facilitate reduction in the pathogen loads of the original stock material. Refer to Appendix C of this EIS for a description of BSA management practices. Appendix C also details how these amendments are treated and land-applied to cropland.

Applying both treated and untreated BSAs of animal origin to produce growing areas is not only a nutrient source, but also a way of disposing of what would otherwise be a waste product. Farmers do this according to their own practices, as efficiently as possible; and changes to their practices could alter the efficiency. Manure is collected and can be used beneficially for agricultural purposes such as seed, grain, oil seed, or forage crop production, or for produce growing. Manure is a valuable commodity not only for raising crops but also for land reclamation and for composting for residential/landscaping uses. In certain circumstances, manure generating facilities pay manure brokers to haul manure away; and in most instances this is put to beneficial uses such as fertilizing crops or landscaping, additions to composting facilities including mixed compost (including yard waste and vegetation), for inoculating biogas production in landfills, for land reclamation (e.g., on reclaimed surface mines, or for landfill cover caps), and other uses. In only rare occurrences would manure be treated as "waste", and therefore disposed of, and not as a resource. Such instances might be if the lot is contaminated with parasites or disease requiring actions other than aerobic digestion or composting that would normally destroy or reduce the pathogens.

Table 3.4-2 below shows surveyed fruit and vegetable produce growers' sources of applied manure soil amendments, in terms of percentages of farms and percent of acres in 1999.

Table 3.4-2. Source of applied manure in program states

Crop Category/Unit	Local		Transported
	On-Farm Manure Source	Other Farm Sources of Manure	Commercial Manure Broker Supplier
All Fruit, Farms	37% of farms	16% of farms	47% of farms
All Fruit, Acres	11% of acres	29% of acres	59% of acres
All Vegetables, Farms	24% of farms	29% of farms	47% of farms
All Vegetables, Acres	10% of acres	23% of acres	66% of acres

Source: USDA NASS, 2001

Therefore, it is apparent that slightly more than half of the surveyed produce farms, (but less than the majority of the acreage on fruit and vegetable farms), which generated either on the same operation or on a neighboring operation (within convenient/inexpensive tractor hauling distance). It is also evident that commercial manure brokers supply manure to a large (but not majority) portion of the operators using animal manure and composted manure.

Roughly 8 percent of fruit farms and 6 percent of fruit farm acres; and roughly 9 percent of vegetable farms and 10 percent of vegetable farm acres; use manure (including both untreated and treated/composted BSAs of animal origin) as their nutrient supplement source; but as discussed earlier in this section, more produce growers actually use elemental fertilizer than use BSAs (USDA NASS, 2001). Crop rotation and cover crops are also practices used by produce growers to maintain fertility instead of (or in addition to) using untreated (raw manure) or treated (composted) BSAs of animal origin or fertilizers.

It is also helpful to understand if growers are using solid manure/compost products (e.g., poultry, horse) or slurry (e.g., cattle) and liquid manure (like swine). The largest source nationally of manure on both fruit and vegetables is cattle manure (combining beef and dairy in Table 3.4-3 below indicates 67 percent of fruit and 41 percent of vegetable growers sourcing their BSAs from cattle farming); followed by poultry manure (20 percent of fruit and 39 percent of vegetable growers sourcing their manure from poultry farming). Therefore, most manure is a solid (poultry; dried/aged/composted cattle; possibly containing bedding material) or semi-solid / slurry (fresh cattle) manure sources.

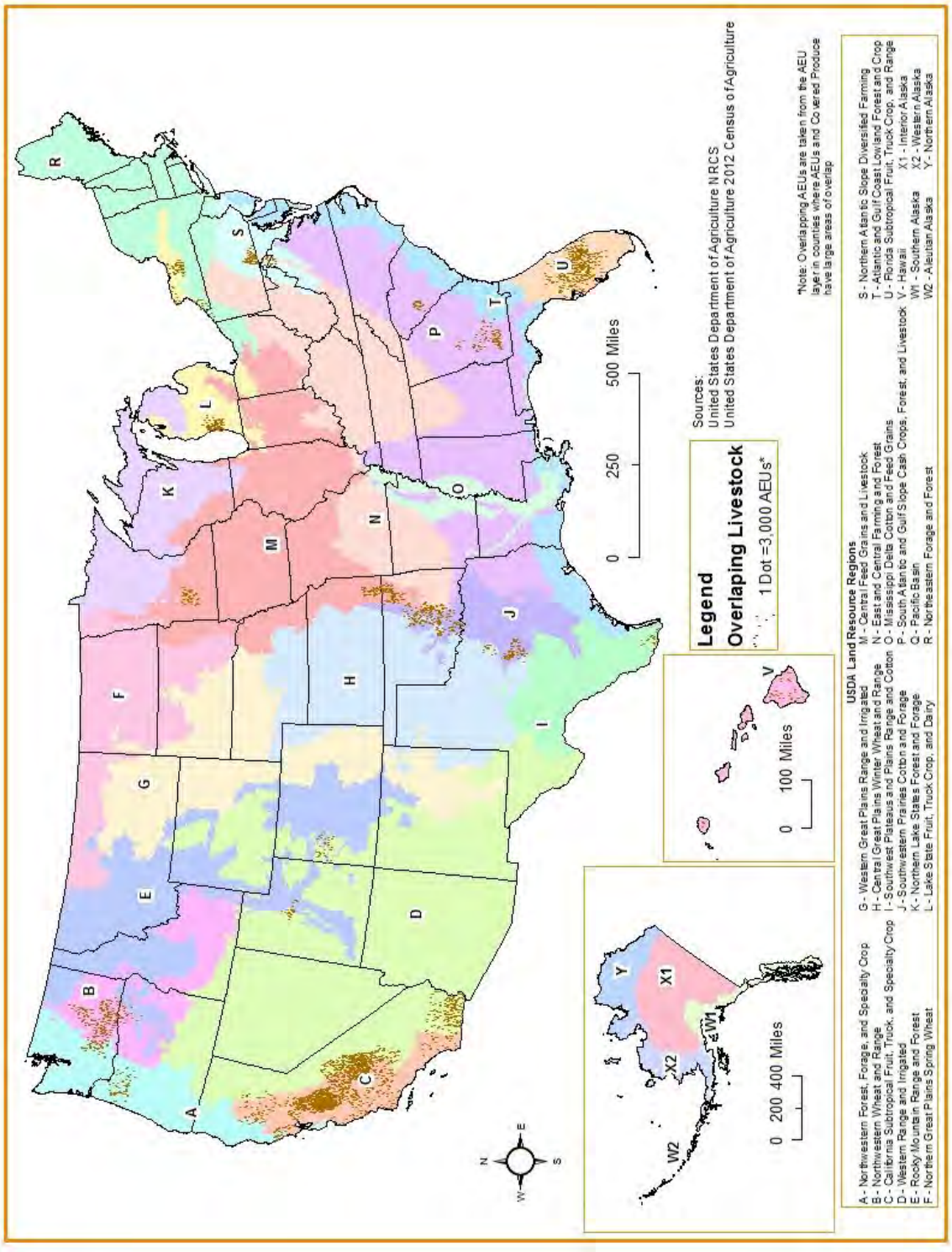
Table 3.4-3. Fruit and vegetable grower agricultural practices; type of manure applied; percentage of acres in program states, 1999

Crop category	Beef Cattle	Dairy Cattle	Swine	Sheep	Poultry	Equine	Other	Total
All Fruit	22	45	0	*	20	*	12	99%
All Vegetables	18	23	(<1)	(<1)	39	9	11	100%

* Insufficient data.
<1 Less than one percent. Sources: USDA NASS, 1999 and 2001

To understand the affected environment in terms of BSAs of animal origin generation, beneficial use and disposal, FDA undertook analysis to ascertain the relative regions where animal agriculture and produce production coincide most. Using the USDA NASS 2012 Census of Agriculture, FDA generated a map correlating the areas of intensive produce growing, with the areas of the most intense livestock and poultry production for purposes of understanding which regions of the U.S. have the greatest potential for using BSAs of animal origin for growing produce (Figure 3.4-1). Other smaller areas are undoubtedly present, but not in widespread concentration where the greatest degree of interrelationship would occur at the scale shown on the map.

Figure 3.4-1. Overlap of most likely areas of covered produce growers and largest concentrations of livestock/poultry animal operations (3000 AEU)



The most noticeable concentrated areas where both animal production and produce growing occur are shown on Figure 3.4-1 and occur within eleven primary regions identified to be important for covered produce in this EIS; these regions include: A, B, C, D, J, M, L, P, S, U, and V. These eleven regions become the areas where BSAs of animal origin are likely used the most. Therefore these regions represent the largest potential for changes in handling requirements for BSAs, and where the PS PR could have the most effects on both the animal/animal products industry, and the minority portion of produce industry growers whose management practices involve using BSAs of animal origin as a preferred soil amendment.

Below is a synopsis of treated and untreated BSA of animal origin.

Untreated

Untreated BSAs are primarily animal "manure" which contains a number of different organic materials in contact with animals and enteric bacteria stock including potential pathogens. The following organic materials (alone or in combination) are constituents of Untreated BSAs of animal origin.

1. Domesticated animal excreta from poultry, livestock, and other animals, in solid, liquid, semi-solid or slurry forms, which can include either
    - Fresh or raw; or
    - Stacked or aged (kept for a period but not treated by aeration and turning)
2. Non-fecal animal by-products including, *et alia*, [bodily fluids, blood, mortalities, dander (e.g., feathers, fur, etc.), egg shells, and other byproducts of animal housing, slaughter, and rendering]
3. Soiled bedding material, feed
4. Post-consumer table waste (i.e., any food scraps from human food or animal feed, and of any type – either meat or vegetable, raw or cooked)
5. Any non-animal origin biological material contaminated with any of these materials (including special considerations discussed below) and
6. Fish emulsions

Chapter 2.1 identifies the number of farms that would be covered under the PS PR, the number of produce acres, and a breakdown of the number of manured acres. Of the 35,503 estimated farms that would be covered by the PS PR (based in 2014 estimates), approximately 821 farms use raw manure, equating to about 70,134 manured acres. There are no available data that identifies the locations of farms that specifically use untreated (or treated) BSAs aside from the information that may be extrapolated from Figure 3.4-1.

The 2001 NASS survey of fruit and vegetable producers in states (accounting for more than 80 percent of produce growers) reported that on average, 3.2 tons of manure were applied per acre per year on fruit operations; and 3.1 tons per acre per year were applied on vegetable operations (USDA NASS, 2001). The fruit and vegetable survey was conducted in 1999, before the establishment of the National Organic Program in 2002. According to studies conducted by the University of Wisconsin Extension, one Animal Equivalent Unit (AEU) or 1,000 animals (identified as bovine) produces approximately 15 tons of manure per year (UW-Extension,

2014). At those average application rates, one dairy cow produces enough manure for nearly seven acres of crops per year.

The methods and timing of application of BSAs of animal origin are discussed in Appendix C (Manure Memorandum). In general, land application of manure can be via injection of liquid forms, or broadcasting of solid and slurry usually followed by incorporation to minimize volatilization of ammonia nitrogen and for aesthetic principals. Optimization for plant uptake of phosphorus (P) is slow because phosphorus (often the limiting element) is not as mobile as nitrogen (N). For this reason, among others, manure is frequently supplemented by side dressing with fertilizers. Also, in part because nitrogen compounds in untreated manure could damage the plants, it generally means that untreated BSA materials are applied prior to planting or during planting; not during the growing season. However, if midseason soil testing would indicate deficiencies of nutrients, a grower would need to supplement by topdressing or side dressing with additional macronutrients (N/P/K), generally accomplished with specific elemental, chemical fertilizer to meet the N/P/K plant requirements.

Table 3.4-4 shows the trends in untreated manure use in growing all crops (not just potentially covered crops). Trend data shows that over the last 15 years approximately 72,165 fewer farms are using raw manure. The amount of crop acres where manure is applied decreases slightly.

Table 3.4-4. Trends in use of raw manure (untreated BSAs of Animal Origin) from 1997 to 2012

Year	1997	2002	2007	2012
Total All U.S. Farms Using Manure [b]	No data	347,585	307,073	275,420
Trend in # Total U.S. Farms Using Manure	No data	Not quantifiable	-2.3%/year	-2.1%/year
Total All Farm Manure Acreage [b]	No data	22,749,251	22,096,315	22,070,968
Trend in # Acres Using Manure	No data	Not quantifiable	-0.057%/year	-0.023%/year

Sources: [a] NASS ERS, 2013b and
[b] USDA NASS: 2014a, 2009a, 2004 (derived from respective 2012, 2007, and 2002 Censuses)

Mixed Soil Amendments

Agricultural teas, green manure, pre-consumer vegetable matter, and any other organic matter would also be classified as being an untreated "BSA of animal origin", *if* the producer of these products is using animal manure as the activation/starter medium, or if the product is contaminated or mixed in part or in whole by untreated BSAs of animal origin. Likewise, agricultural teas that use agricultural water that does not meet the microbial standards of the PS PR, or that have incorporated agricultural tea amendments (e.g., addition of molasses to bolster microbial populations) would also be classified as untreated BSAs of animal origin, irrespective of the original feedstock used.

Treated

Any of the above "Untreated" materials of animal origin subjected to physical, thermal, chemical, or biological treatment (such as by the controlled prescribed composting treatment processes described in the PS PR), or a treatment in combination with any of these to eliminate or substantially reduce pathogens to meet proposed microbial reduction standards (proposed §112.55(b)). Examples include pelletized poultry manure, dried blood meal, rendered/steamed bone meal, treated feather meal, or composted manure processed according to the provisions of the PS PR.

This also includes BSAs further treated to reduce pathogens to the more stringent microbiological standards presented in the PS PR (proposed §112.55(a)). For example, the two-phase "pasteurization" process for preparing mushroom mulch.

The storage of BSAs of animal origin, including storage for treatment can contribute to issues such as off-gassing (releasing nitrogen in the form of ammonia) as discussed in the Chapter 3.5 Air Quality, and runoff that can enter surface waters as discussed in Chapter 3.1 Water Resources.

Of the 35,503 estimated farms (based in 2014 estimates) that would be covered by the PS PR, approximately 3,618 farms use treated BSAs of animal origin, equating to about 430,828 produce acres. There are no available data that identify the locations of individual farms that specifically use treated BSAs of animal origin. Therefore, pinpoint locations within general regions of predicted impact shown on Figure 3.4-1 are not possible at this level of analysis. Farms using treated BSAs of animal origin exist outside of the co-location livestock/produce concentration areas as well; and not all of the areas indicated on Figure 3.4-1 would have either individual or community composting facilities for BSAs of animal origin.

3.4.3.2 Domesticated Animal Considerations

Domesticated animals can occur in a growing area for several reasons such as (1) draft or working animals; (2) animals allowed to graze on unharvested portions of produce; or (3) animals introduced for co-management practices (e.g., to control insects). Draft animal use is not typical except on old order (Anabaptist) farms, because the large majority of modern farming uses mechanized machinery. Grazing on unharvested fields would be limited to certain crops suitable for forage, and timed mostly to occur following the growing season. Co-management for insect control is not a common practice. Therefore, given all three of these considerations, it is anticipated that the involvement of domesticated animals would introduce a relatively minor opportunity for involving manure in produce growing areas.

While draft animals were used extensively in farming until the mid-20th Century, engine- or motor-driven mechanized farm machinery has quickly and largely replaced the ox, mule, and horse for plowing and pulling on U.S. farms. The exceptions to this overall trend include Plain Sect agriculture practices (e.g., Amish and Old Order Mennonite, or conservative Anabaptist farmers) and uncommonly encountered farms in similar conventional traditional agrarian

communities. Plain Sect farms sometimes contract out their plowing and pulling work, but most communities or congregations are restricted from owning and otherwise using powered machinery. For those who choose to not contract out plowing, planting, and pulling, draft animals (oxen, mules, and horses) are their principal option for cultivating and heavy hauling in fields. Amish communities exist in 30 U.S. states; with the largest communities primarily in Ohio, Pennsylvania, Indiana, Wisconsin, New York, Missouri, and Montana. Mennonite communities are similarly widespread and flourish in the same farming areas as well as California, Illinois, and Kentucky. Due to subdivision of farm inheritance among siblings, in some areas where farm property for expansion of the community is limited, the land available for a farm family to make its living is considerably comparatively small. For example, the average Lancaster County, Pennsylvania farm is 78 acres (Komancheck, 2013); which is not enough land to produce yields sufficient to support farming as a sole income based on grain production. Therefore, specialized farming such as livestock farming and/or growing a high-value crop like tobacco or fresh produce is necessary to maintain suitable returns to make farming a viable sole livelihood for these small family farms.

3.4.3.3 Application to Harvest Intervals

A brief explanation of application (of BSAs of animal origin) to harvest intervals will assist the reader in understanding the potential relationship between application of BSAs of animal origin as proposed under the PS PR and the growth cycle requirements for certain crops covered by the PS PR. Fast-growing produce crops with harvest cycles 45 days or less from planting of seed are few, and include those listed on Table 3.4-5. Most fresh produce crops have full summer planting to harvest cycles, varying over 45 days to under 120 days (Table 3.4-5). While parts of the U.S. only get one crop per year (notably the northeastern regions such as region R as shown on Figure 1.7-4), other parts of the U.S. (notably the subtropical regions including regions B, C, D, and U, can achieve multiple – double- or triple- cropping within one year. Another consideration is that some produce crops have multiple harvest cycles. That would include perennials or biennials, e.g., caraway, fennel, mints, young sorrel, and strawberry (Dolezal, 1991), which could allow successive harvests in less than 45 days.

BSAs of animal origin may generally be applied pre-planting, or in some cases at the time of planting, or during growing (e.g., side dressing). USDA and state nutrient management regulations recommend against or prohibit application when the ground is frozen; and therefore fall (post season) or spring (pre-planting or during planting) application of are strongly advocated. What is not well documented is if or when BSAs of animal origin are applied between the harvest intervals for crops with shorter seed to harvest durations (Table 3.4-5). It is also possible that a combination of soil amendments may be used during these periods, such as elemental/chemical fertilizers. Because top dressing with manure can damage the plants, side dressing is a more attractive option, and would be done to supplement crop needs if optimal nutrients were not applied prior to planting.

Table 3.4-5. Harvest cycles for example produce

Fresh Produce Commodity Type	Seed to Harvest Cycle Duration	45 Days or Less -- *Fast-growing*	Less than 90 Days (3 mo.) -- *Full-summer*	>90-120 Days (4 mo.) -- *Long-season*
Baby Lettuce/Greens	40 days	✓***		
Bean, Snap	54 days		✓	
Beet	58 days		✓	
Cantaloupe	86 days		✓	
Carrot	68 days		✓	
Cauliflower	70 days		✓	
Celery	105-130 days			✓
Cucumber	57 days		✓	
Endive	95 days			✓
Garden cress	vary 45-70 days		✓	
Garlic	90-100 days		✓	
Kohlrabi	45-60 days		✓	
Lettuces	45 days*	✓		
Melon	110 days			✓
Most herbs	vary by type**, 30 – 60 days	**some**	✓	
Mustard greens	30 days	✓		
Onion, Drying	110 days			✓
Onion, green	60-110 days	(from bulbs)	**Some** (from seed)	✓
Pea, English Garden	60 days		✓	
Pea, Snap or Snow	70 days		✓	
Radish	26 days	✓		
Roquette or Arugula	35 days	✓		
Spinach	45 days ***	✓	✓ (multiple cuts)	
Summer Squash	50 days		✓	
Tomato	80 days		✓	
Turnip	45 days	✓		
Watermelon	73 days		✓	

Source: Dolezal, 1991.

* Head and romaine lettuce mature about 70 days from seeds and 20-35 days from transplants; leaf lettuces at about 45 days from seed.

** Basil 30 days, Chervil 40-60 days, Chinese parsley 40-45 days, Cilantro or Coriander 30-40 days, Dill 25-30 days, Oregano 35 days, Parsley 45-60 days, Sage 35 days, Savory 42 days, Sweet marjoram 40-45 days

*** Successive spinach and greens cuttings occur at more frequent intervals

USDA and Industry Application to Harvest Intervals

In general terms, GAPs recommend avoiding side dressing with raw manure, but instead apply manure and incorporate it prior to planting. In addition, GAPs recommend using treated (composted) material instead of raw or aged manure; and to apply it as early as possible for both maximal plant uptake as well as to avoid contaminating produce with pathogens (FDA, 1998).

USDA organic regulations (7 CFR Part 205) suggest the use of treated (composted) manure instead of untreated manure, however if untreated manure is used, then:

- 90 days between application and harvest are required if the harvested portion of the crop does not contact the soil (e.g., corn or fruit trees); or,
- 120 days between application and harvest if the harvested portion of the crop could contact soil during the growing season (e.g., bush crops, vines, root crops, leafy greens, etc.).

The nature of the difference is such that a farmer complying with the PS PR would still be in compliance with the USDA organic regulations requirements for BSAs.

The California Leafy Greens Marketing Agreement (CA LGMA, 2013) and Arizona LGMA (AZ LGMA, 2013) both have the following restrictions on BSAs of animal origin:

- The grower should not use untreated (raw) manure in edible crop production; and for previously treated fields, a one-year waiting period shall be observed before planting any variety of leafy green crops (the same preclusion or waiting period also applies to California's cantaloupe marketing agreement).
- For treated (composted) manure, if microbe levels are below corresponding action level numbers, then an application time interval of at least 45 days before harvest must be observed.
- For further treated physically processed (heated) products, according to the LGMA guidelines for non-validated process, an observe application time interval of at least 45 days before harvest; or for validated process, no application to harvest interval is required.

The Tomato Food Safety Audit Protocol (NATWWG and United Fresh, 2008) requires that only properly composted manure is allowed for use in tomato fields and greenhouses.

Mushroom Good Agricultural Practices (Penn State and AMI, 2010) currently require that producers receive and store materials in a manner that avoids the potential for cross contamination between mushrooms and an unpasteurized substrate (i.e., require processed BSAs of animal origin, exclusive to untreated or simply treated compost that are not pasteurized).

Relative Risk of Produce Contamination

Together, the combined types of covered produce constitute the single largest category of foodborne illness cases attributed to a single food and over twenty commodities accounted for serious reported outbreaks of disease during the study period from 1996-2010 (FDA, 2013c). FDA's Draft QAR indicates in its exposure assessment that sources of contamination are influenced by input (pathogen load) and survival of pathogens in the environment, and examines the pathways of pathogen transfer. Enteric or gastrointestinal pathogens are generally not considered to be derived outside of a host animal or human source (FDA, 2013c) but can persist in the environment depending on factors including their original input. Animal excreta are considered to have a relatively high potential for harboring zoonotic pathogens such as *Salmonella* species (FDA, 2013c).

Table 3.4-6 illustrates in general terms how different factors related to soil amendments used in growing produce influence the relative likelihood of produce contamination (FDA, 2013c). Much depends on the type(s) of soil amendments added, and the type and degree of treatment the material receives prior to being applied to the growing area soils (FDA, 2013c). In addition, the application method and application timing also influence the likelihood of contamination (FDA, 2013c). Note that non-biological soil amendments are not within the scope of the PS PR, because they present at lower relative risk in terms of biological contamination of fresh produce, no matter if applied prior to or during planting, or as a side dress during the growing season.

Table 3.4-6. Produce contamination from soil amendments

Relative likelihood of produce contamination	Least  Most			
Type of BSAs	Non-Biological	Non-Animal Origin	Animal Origin	Human Waste
And where pathogens exist in the BSA source(s), the likelihood of contamination is a function of pathogen load that is influenced by the following factors:				
Treatment	Pasteurized (heat, chemical, and physical destruction of microbes)	Composted (a.k.a., "Treated")		Untreated/Raw or Aged; Partially Treated; Re-Contaminated
Application Timing	Increased Duration between Application and Harvest Time		Decreased Duration between Application and Harvest Time	
Application Method	No Contact with Harvestable Portion	Effort Made to Minimize Contact		Contact with Harvestable Portion

Source: FDA, 2013c

3.4.3.4 Transportation Related Considerations

There are costs associated with transporting BSAs of animal origin for any distance that could make beneficial reuse uneconomical; therefore, there may be opportunities for technologies that reduce the moisture content of manures to improve efficiency if local disposal becomes an unattractive option. Air quality conditions relative to transportation are addressed in Chapter 3.5.

3.4.3.5 Methods to Analyze Impacts

Summary of Data Collected

Of the approximately 35,503 farms that would be covered by the PS PR, approximately 4,438 farms (12.5 percent) used BSAs (Chapter 2.1). Of the 4,438 covered farms using BSAs, approximately 820 farms used untreated BSAs (raw manure). An estimated 3,618 farms (81.5 percent) use treated BSAs (composted manure). The remainder of covered farms (approximately 87.5 percent) may use chemical fertilizers.

There are eleven regions where BSAs of animal origin are likely used the most; therefore these regions represent the largest potential for changes in handling requirements for BSAs of animal origin: A, B, C, D, J, M, L, P, S, U, and V.

USDA NASS data (2001, 2002, 2007, and 2012) shows a downward trend in the use of both untreated manure and chemical fertilizers (Chapter 3.1.3.1, Table 3.4-1).

While most crops have a seed to harvest interval of approximately four months, intervals for application of BSAs of animal origin to crop harvest vary by federal (organic regulations) and industry marketing agreements. USDA organic regulations have shorter application to harvest intervals (90/120 days), while some marketing agreements may have application to harvest intervals of up to a year (Chapter 3.4.3.3). FDA found no data to suggest on a consistent basis if and when BSAs of animal origin are applied between the harvest intervals for crops with shorter seed or transplant to harvest durations (between double or triple cropping intervals), or if other soil amendments may be used during these periods, such as chemical fertilizers.

Facilities that may store raw manure and may perform composting operations (e.g., CAFOs) are sometimes required to apply for a NPDES permit, if those facilities discharge or propose to discharge. Therefore, if the facilities are operated and maintained in accordance with their permits, under normal circumstances there are processes in place to protect against adverse harm to the environment (effects from run-off). It may be noted that significant rain events, for example, may contribute to unintentional discharges to receiving waters.

The leafy greens industries in California and Arizona implemented marketing agreements in 2007 that impose food safety requirements on participating growers. The CA LGMA covers approximately 99 percent of the volume of leafy greens produced by the state (380 farms), and the AZ LGMA covers approximately 41 farms that would be covered by the PS PR. The AZ

LGMA accounts for approximately 85 percent of the leafy greens products consumed in the U.S. and Canada from November to March (FDA, 2013b).

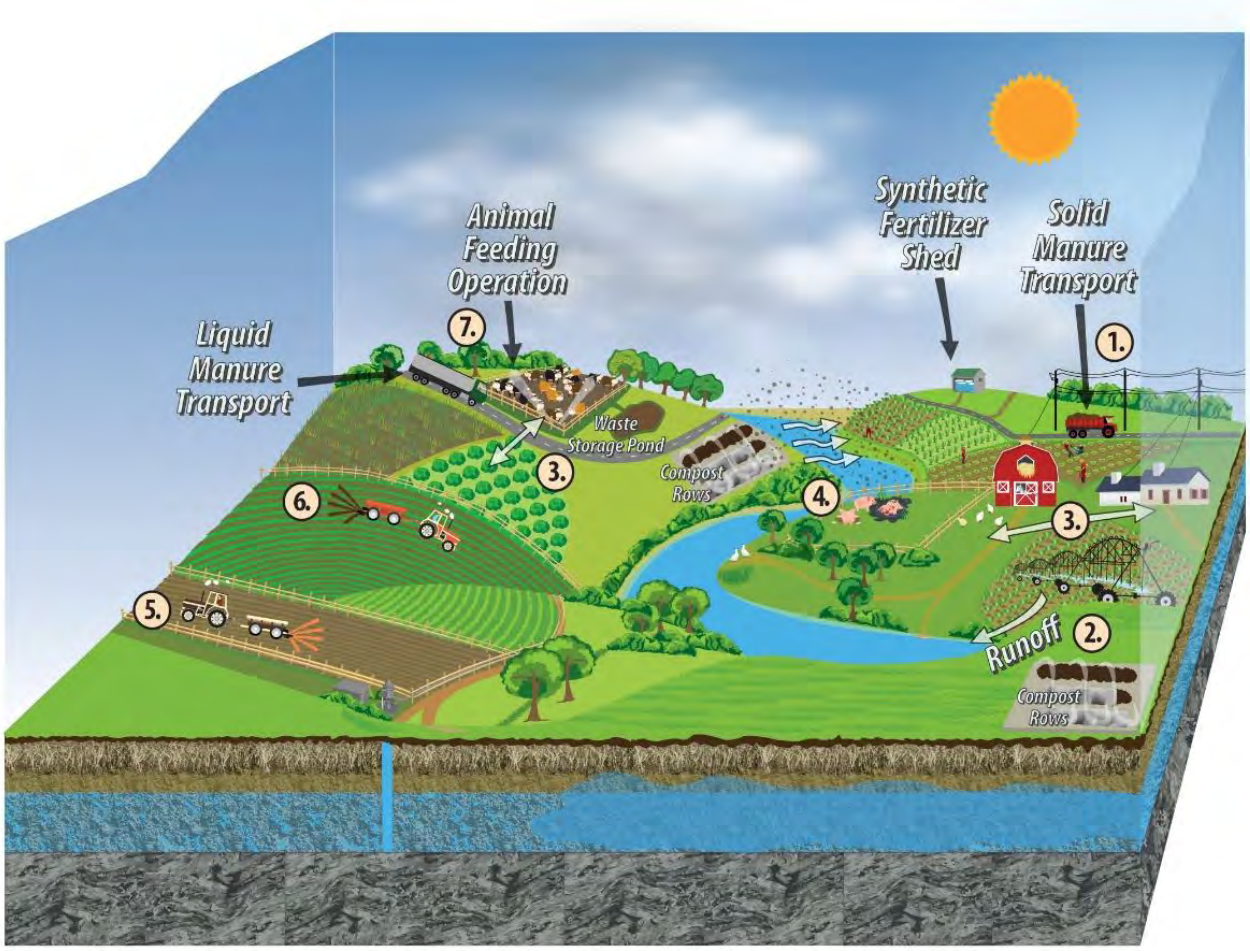
Conceptual Site Model

Figure 3.4-2 illustrates many of the major operations, activities, and processes that contribute to waste generation on working produce farms that may be affected by the PS PR. This graphic summarizes information described within this chapter in order to most comprehensively represent the types of activities that may be affected by the various provisions of the PS PR. The following provides a summary of the major activities that are depicted in Figure 3.4-2:

- **Land Application of Manure**: Application of manure (followed by incorporation) is best done after the harvest (as depicted in the lower illustration), or on cover crops that are plowed under prior to planting (as depicted in the upper illustration).
- **Animal Feeding Operations**: Facilities where manure is generated and collected, for beneficial use onsite and/or offsite.
- **On-Farm and Off-Farm Static Composting Operations**: Facilities where manure is treated to achieve thermal and temporal requirements.
- **Best Management Practices and GAPs**: As outlined below in the Key Components list, the Conceptual Site Model diagram also illustrates measures that can be taken by animal producers and produce growers for environmental and economic benefits.

The Key that follows contains text that applies to numbered key components of the diagram.

Figure 3.4-2. Conceptual site model for animal waste good agricultural practices and conservation measures.



Key to numbered illustrations within Conceptual Site Model (Figure 3.4-2)	
1	● Growers purchasing manure products should obtain a specification sheet from the supplying manure broker for each shipment, and the spec sheet should include information about the method of treatment
2	● Implement practices to avoid potential of contaminating treated manure ● Consider GAPs and conservation measures to minimize leachate from manure storage or treatment areas from contaminating produce growing and handling areas
3	● Manure storage and treatment sites should be situated as far as practicable from fresh produce production and handling areas
4	● Consider barriers or physical containment to secure manure storage or treatment areas where runoff, leaching, or wind spread is a concern
5	● Incorporating manure into soil prior to planting; (applying raw manure or leachate from manure to produce fields during the growing season is not recommended ● Use cover crops (a.k.a., Green Manure) instead of or in addition to BSAs of animal origin applied after harvest (during the off season) to build soil fertility
6	● Maximize time between application of manure to produce production areas, and harvest; or use treated manure instead of raw or aged manure ● USDA Certified Organic standards require application of composted manure (treated according to specific standards including C:N ratio, timing/aeration or turning, temperature minimums); or if untreated / aged manure is used then an application to harvest duration is required (120 days for crops whose edible portion contacts the soil; 90 days for all other crops) (USDA AMS, 2014)
7	● Growers should consult state and local manure handling expertise for specific advice for their region and individual operation; this includes agricultural colleges and cooperative extension service agents with specific expertise ● Domestic animals should be excluded from fresh produce fields, vineyards, and orchards during the growing season (confinement in pens or yards) ● Growers should implement measures to ensure that BSAs of animal origin from adjacent fields or waste storage facilities does not contaminate the produce production areas

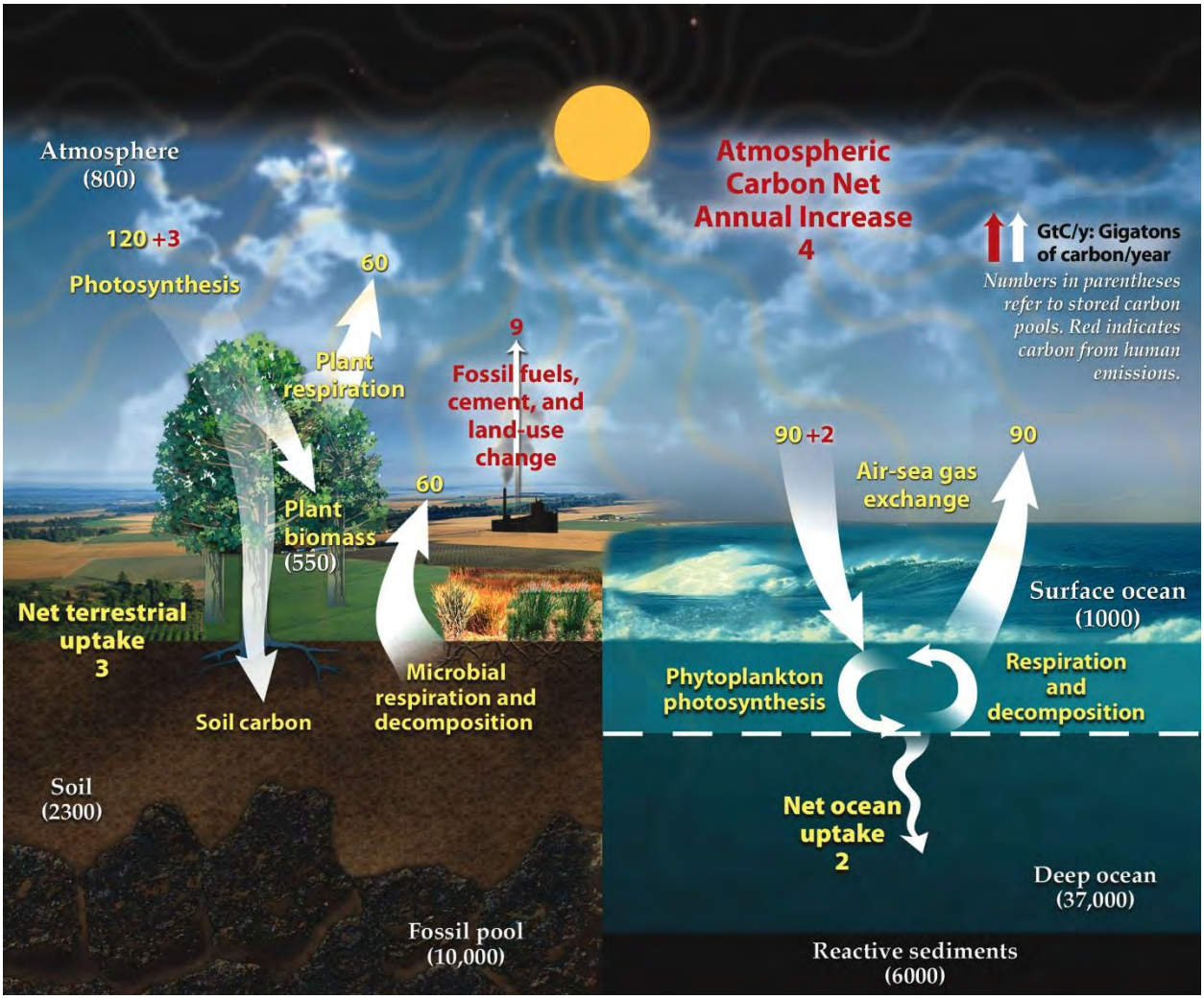
Source for Key text: FDA (1998), except where otherwise indicated.

3.5 Air Quality and Greenhouse Gases

3.5.1 Definition of the Resource

Scientists have become increasingly interested in the impacts of human activities on global temperature and climate change, spurring the EPA to identify carbon dioxide (CO_2), methane (CH_4), and nitrous oxide (N_2O) as the most important long-lived GHGs related to warming temperatures in the atmosphere. Although all of these gases occur naturally in the atmosphere, human activities have significantly increased the concentrations of these gases. Since the beginning of the industrial age in 1750, concentrations of CO_2, CH_4, and N_2O have increased by 38 percent, 143 percent, and 18 percent, respectively (USDA CCPO, 2011).

Figure 3.5-1. Components of the global carbon cycle (DOE, 2013)



The process by which carbon moves between the atmosphere and different reservoirs in the earth is called the carbon cycle. The main reservoirs in which carbon can be stored include the atmosphere, the oceans (in dissolved inorganic carbon and marine biota), the earth's interior, the terrestrial biosphere (living and dead organisms), and sediments including fossil fuels and SOM. The movement of carbon among these reservoirs occurs through a variety of chemical, physical, geological, and biological processes. Major components of the global carbon cycle include: (1) the conversion of atmospheric CO_2 into organic compounds through photosynthesis in plants and phytoplankton; (2) the consumption of carbon and respiration of CO_2 by plants, animals, and microbes; (3) SOM formation; and (4) the return of CO_2 to the atmosphere. Carbon can move quickly within this cycle or may be stored in reservoirs for long periods of time (Denman et al., 2007). Humans can have large effects on the carbon cycle through burning fossil fuels and altering land uses. Figure 3.5-1 illustrates the carbon cycle.

3.5.2 Regulatory Oversight

The Clean Air Act (CAA) (42 U.S.C. § 7401 et seq.) requires EPA to set National Ambient Air Quality Standards (NAAQS) for pollutants considered harmful to public health and the environment. EPA has established NAAQS (40 CFR Part 50) for six criteria pollutants, which include carbon monoxide (CO), lead (Pb), nitrogen dioxide (NO_2), ozone (O_3), sulfur dioxide (SO_2), and particulate matter (PM) between 2.5 and 10 micrometers in diameter (coarse, PM_{10}) or that is less than 2.5 micrometers in diameter (fine, $PM_{2.5}$). Primary NAAQS provide public health protection, while secondary standards protect against welfare effects such as damage to farm crops and vegetation (EPA, 2012b).

The CAA mandates that each state achieve and maintain acceptable levels of the six criteria pollutants. If areas have levels of pollutants that are higher than the acceptable limits set by EPA, then the area is deemed a nonattainment area for the specific pollutant. The CAA requires states to develop a written State Implementation Plan (SIP) that outlines how the state will control air pollution under the CAA (EPA, 2013b). Each SIP consists of regulations, programs, and policies that will aid the state in reducing air pollution in (EPA, 2013b). State and local governments also conduct air quality monitoring and facilities inspections to enforce CAA regulations (EPA, 2014i). Once a nonattainment area meets the standards and redesignation requirements for attainment, EPA designates the area as a "maintenance area" (EPA, 2013b). Therefore, maintenance areas represent areas that used to be in nonattainment but continue to be monitored by the EPA following redesignation to attainment.

3.5.3 Current Background Conditions

Resources Used to Establish Existing Environment for Air Quality

Information and data on criteria air pollutants and GHGs were gathered in order to establish the existing environment at both a national and regional scale. Data from EPA on emissions of criteria air pollutants by source sector were compiled to provide a broad scope of agricultural impacts on air pollution and NAAQS in the United States. In addition, non-attainment area maps were generated in order to illustrate the regions and states that feature the most existing air

quality problems. Data related to national and state-level GHG emissions were pulled from two major sources: (1) the EPA *U.S. Greenhouse Gas Emissions and Sinks: 1990-2012* report (EPA 2014k); and (2) the USDA *U.S. Agriculture and Forestry Greenhouse Gas Inventory: 1990-2008* report (USDA CCPO, 2011). Areas of covered farms and associated livestock operations were also overlaid on maps in order to show where air quality resources have the biggest potential to be impacted regionally with regard to the PS PR.

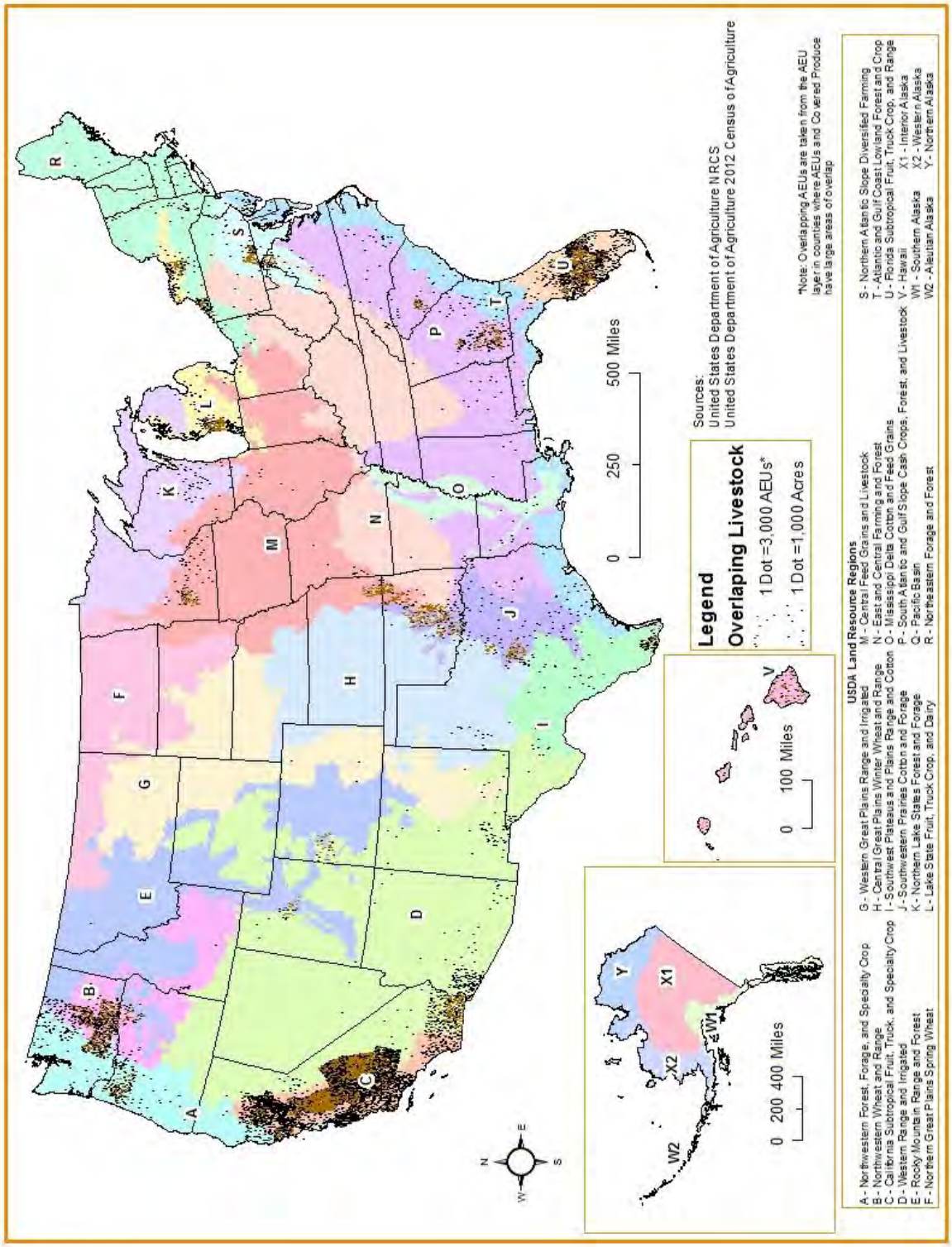
Affected Environment Summary – Covered Farms under the PS PR

Farming operations that are likely to be affected by the PS PR include both cropland and livestock agriculture, both of which contribute to total emissions of air pollutants and GHGs. In order to address potential air quality impacts of the PS PR it is important to understand where covered farms and associated livestock operations are located. Figure 3.5-2 depicts USDA 2012 Census of Agriculture dot-density maps for major concentrations of produce producing areas (concentrations of 1,000 acres of produce), and where large concentrations of livestock and poultry operations (3,000 or more animal equivalent units) overlap with these areas. These data are overlaid on our base map, which can be viewed as a base-map illustrating the states and regions which are most likely to experience the largest impacts to air quality resources from the PS PR. Subsequent maps and figures provided in this section (and later referenced in Chapter 4) illustrate aspects of existing air quality with the most significant regions affected by the PS PR.

Figure 3.5-2 shows the most important areas of produce production, coupled with the largest areas of farm animal concentrations within covered produce areas. The most noticeable concentrations occur in just four regions, which are listed below in approximate order of largest produce acreage. Importantly, over roughly 80 percent of the covered produce acreage shown in the map occurs within these four regions:

- **Region C –** Subtropical Fruit, Truck Crop, and Specialty Crop (central California)
- **Region D –** Western Range and Irrigated (southern California, southwestern Arizona)
- **Region U –** Florida Subtropical Fruit, Truck Crop, and Range (south-central Florida)
- **Region B –** Northwestern Wheat and Range (central Washington)

Figure 3.5-2. Most likely areas of covered produce growers and overlap with largest concentrations of livestock/poultry operations



Existing Conditions Summary: NAAQS

Of the six criteria pollutants, particulate matter (also known as particle pollution or PM) emissions are most directly associated with agricultural practices. According to data from the EPA, 896,727 tons of $PM_{2.5}$ and 4,502,018 tons of PM_{10} were released in the U.S. in 2011 from agriculture, mostly as a result of crop and livestock dust emissions (EPA, 2014i). Agricultural practices also indirectly contribute to ground-level ozone (O_3) formation through emissions of ozone precursor gases such as nitrogen oxides (NO_x) and volatile organic compounds (VOCs). Direct agricultural practices are not heavily associated with emissions of the remaining criteria pollutants relative to larger sources such as fossil fuel combustion from the transportation and industrial sectors. However, it is important to note that increases in energy use or mobile transport related to the PS PR could lead to increases in emissions of these pollutants.

The existing NAAQS set the amount of pollution allowed in the outdoor air for each criteria pollutant; however, these standards themselves do not establish emission control requirements for any particular industry, including agriculture. In fact, agricultural operations have often been treated differently than other industries with respect to federal and state laws. Many laws either directly exempt agriculture from regulations or are set up so that farms avoid most of the regulatory impact. With regard to environmental law, regulators have typically focused more attention on larger, more visible sources of pollution (e.g., factories) compared to small farms (Copeland, 2014). It is the responsibly of each state to determine how to reduce a nonattainment area's pollution to meet the NAAQS in their SIP, which must then be approved by EPA. Most agricultural operations are believed to be minor sources of air pollution, and most have not been required to comply with SIP permitting requirements. For individual operations to be required to comply with CAA regulations they typically must meet the definition of a "major source" of regulated pollutants, which can vary by region and whether the source occurs in an existing nonattainment area or not. Most farms do not meet this definition and are therefore exempt from CAA regulations. However, a lack of adequate air quality monitoring data from agricultural operations has often prevented regulators from moving forward with regulations specific to agriculture (Copeland, 2014).

Despite the lack of national-level policies related to agricultural air quality, some states are addressing agricultural emissions of major criteria pollutants (e.g., particulate matter) in their SIP's when the agricultural industry makes up a greater portion of overall emissions. For example, states like California and Arizona, which feature some of the most impaired air quality in the U.S., are addressing PM_{10} from agriculture by incorporating conservation management practices developed with growers and USDA into PM_{10} implementation plans for their nonattainment areas (EPA, 2013c). Air emission permits are now required for many agricultural operations in California, with requirements varying depending on the size of facilities, level of emissions, and attainment status in the area the source is located. However, the lack of sufficiently accurate data on emissions from agricultural activities in general has contributed to resistance from the farming community in implementing laws to regulate agricultural emissions (Copeland, 2014).

Particulate Matter

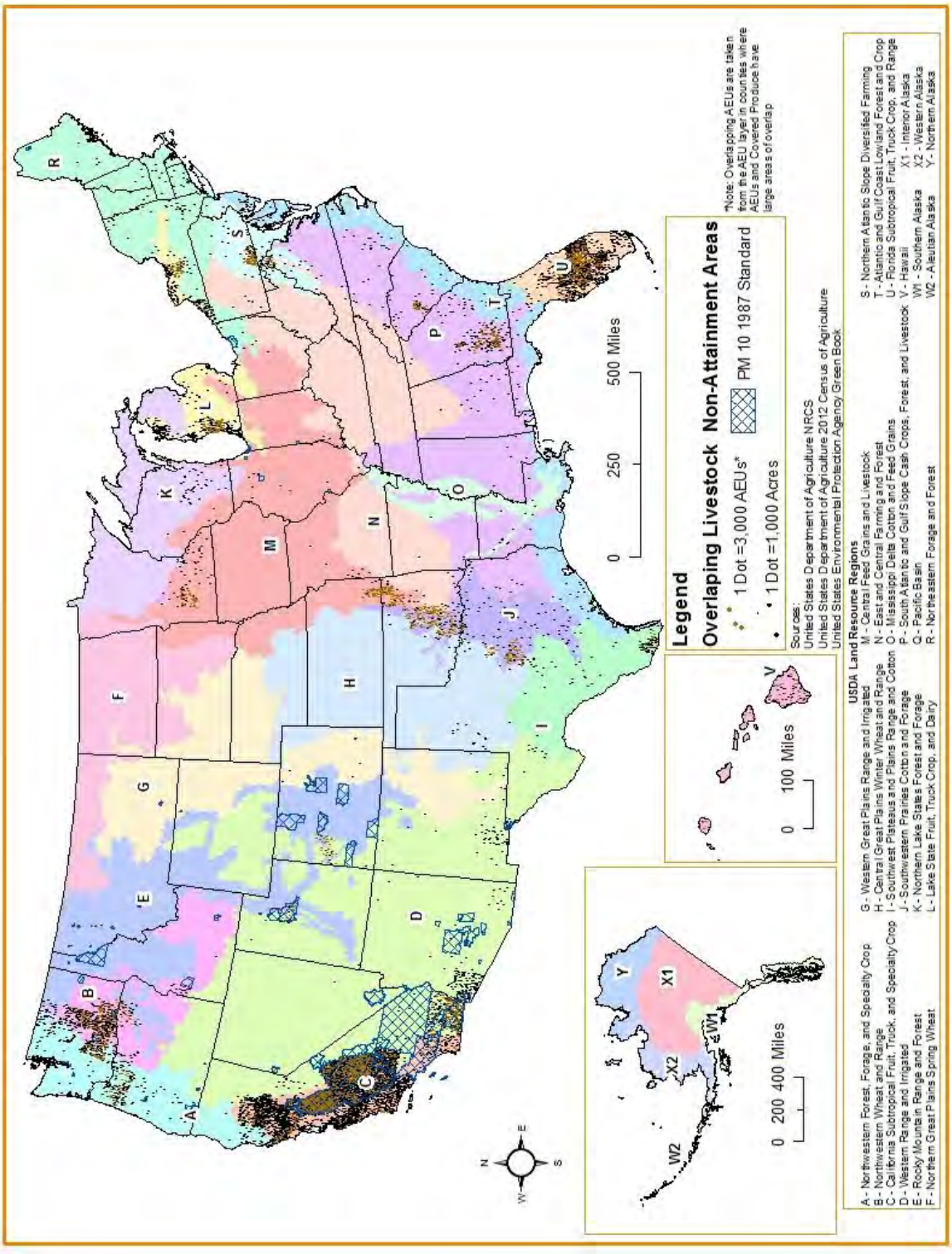
Particulate Matter is a complex mixture of extremely small particles and can be composed of acids, organic chemicals, metals, and soil or dust particles. The EPA regulates particles that are 10 micrometers in diameter or smaller because they can generally pass through the throat and nose and enter the lungs, potentially causing serious health effects such as respiratory and heart diseases and other ailments. Primary particles are emitted from a source, such as smokestacks, fields, unpaved roads, or construction sites. Secondary particles, which make up most of the fine particle pollution in the U.S., form through a variety of chemical reactions in the atmosphere (EPA, 2013d). The majority of states have not required the agricultural industry to establish emission control requirements for PM.

Agriculture is a major contributor to emissions of coarse particulate matter (PM_{10}), which is typically directly emitted to the atmosphere by actions that break up the soil such as road and field travel, tillage operations, animal movement, harvesting, and wind erosion. Fine particulate matter ($PM_{2.5}$) can also be directly emitted to the atmosphere by combustion processes from vehicles and fires. However, a significant portion of fine particulate matter is formed in the atmosphere by chemical reactions with PM precursor gases such as NO_x, VOCs, and ammonia (NH_3). Sources of these precursor gases can include engines, fertilizer application, and animal operations (USDA NRCS, 2012a).

The non-attainment areas for PM_{10} and $PM_{2.5}$ (based on EPA Green Book data) are illustrated in Figure 3.5-3 and Figure 3.5-4, respectively (EPA, 2014j). The highest concentrations of particulate matter non-attainment areas that overlap with covered produce operations occur in central and southern California (regions C and D). Estimates of total emissions of PM_{10} and $PM_{2.5}$ in 2011 by source sector are depicted in Figure 3.5-5 and Figure 3.5-6, respectively (EPA, 2014j). The majority of the emissions attributed to agriculture are a result of crop and livestock dust emissions, with minor contributions from livestock waste. However, PM emissions from unpaved roads and fuel combustion are not included in the agriculture source sector; therefore, the total contribution of the agricultural sector to PM emissions is underestimated in these figures.

Ammonia emissions are becoming a greater health concern in the U.S. (Copeland, 2014). Ammonia is produced as a by-product of the microbial decomposition of the organic nitrogen compounds in manure. Therefore, ammonia emissions may result from any area that contains manure, such as open lots, stockpiles, lagoons and pits, and land application areas (EPA, 2004). Ammonia emissions from liquid manure storage structures rapidly adhere to particles in the air, thereby contributing to the formation of ambient particulate matter (Copeland, 2014). Once emitted, ammonia is also re-deposited back to earth in rainfall, which can impair surface waters and harm aquatic life. The EPA estimates that animal agriculture accounts for 50 to 85 percent of total man-made ammonia volatilization in the United States. In the U.S., livestock and poultry production is the largest contributor of ammonia gas emissions, followed by agricultural fertilization (eXtension, 2012a).

Figure 3.5-3. Coarse Particulate Matter (PM_{10}) Non-Attainment Areas (1987 Standard) (EPA 2014j)



Animal Feeding Operations (AFOs), which refer to facilities designed to hold and grow livestock or poultry in a confined area, are becoming more prevalent in the U.S., and PM emissions from these open-lot AFOs are an increasing environmental concern. Very large operations (housing 300 or more cows or equivalent numbers of other species) are defined as Concentrated Animal Feeding Operations, or CAFOs. Of the approximately 238,000 farms that are considered AFOs, roughly 5 percent raise enough animals to be designated as CAFOs (Copeland, 2014). However, organizational shifts in the industry within the past two decades have resulted in larger facilities that are more concentrated in certain regions. Particulate matter has the potential to carry pathogens that could directly lead to human infection or to the contamination of adjacent produce croplands. In addition to human health impacts, fugitive PM (dust) from cattle feedyards and other farms can reduce visibility and carry odors.

On animal lots, the main sources of primary particulate matter are hoof action on uncompacted manure, vehicle traffic on unpaved roads, feed processing, and fossil fuel combustion. These coarser particles generally impact local environmental air pollution. Secondary PM for CAFOs and other animal operations results from gas-phase NH_3 forming fine particles during atmospheric reactions, which tends to impact regional and national air quality. The highest concentrations of fugitive dust from open-lot AFOs come from hoof action or wind scouring of uncompacted manure (eXtension, 2012b). Revisions of regulations from the CWA to better protect surface waters from nutrient-rich runoff from CAFOs can impact air quality. Livestock operators may respond to required nutrient management plans by allowing nitrogen to volatilize into the atmosphere in uncovered lagoons or by applying waste to fields without incorporation into the soil. These practices may reduce runoff of nutrients into surface waters, but they also cause the release of ammonia emissions into the air, thus contributing to particulate matter emissions as well (USDA ERS, 2005).

Figure 3.5-4. Fine Particulate Matter ($PM_{2.5}$) Non-Attainment Areas (2006 Standard) (EPA 2014i)

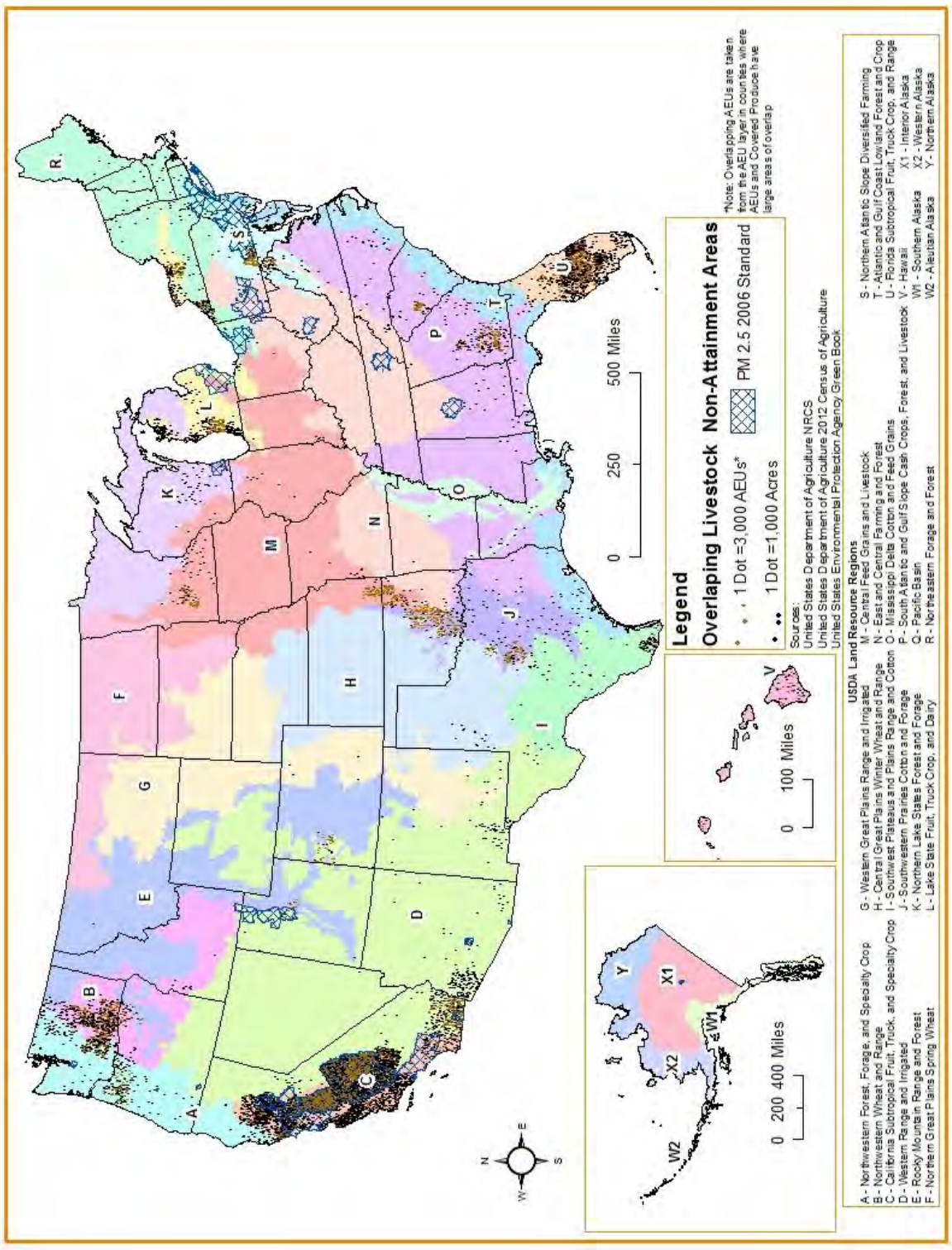


Figure 3.5-5. National PM-10 emissions by source sector in 2011 (EPA, 2014i)

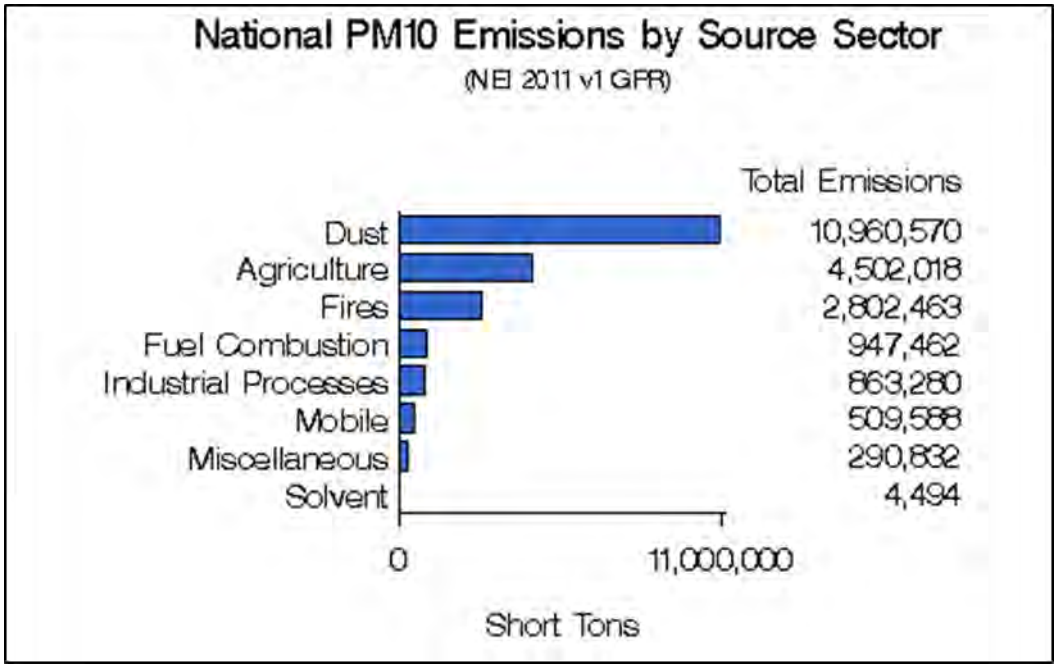
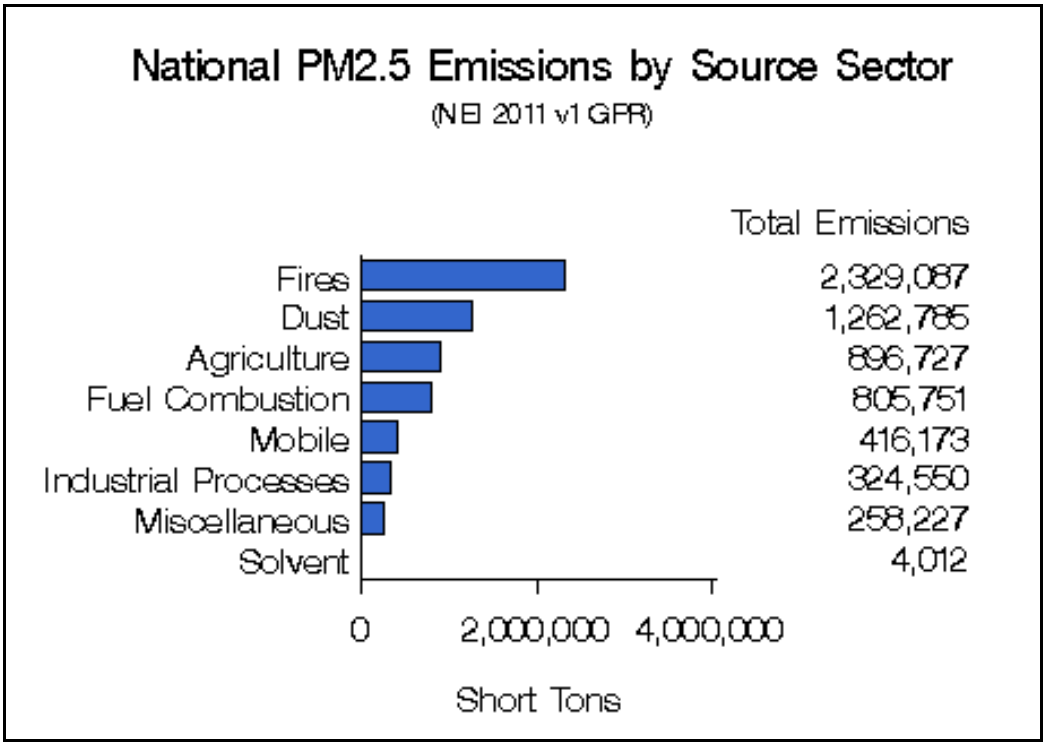


Figure 3.5-6. National PM-2.5 emissions by source sector in 2011 (EPA, 2014i)



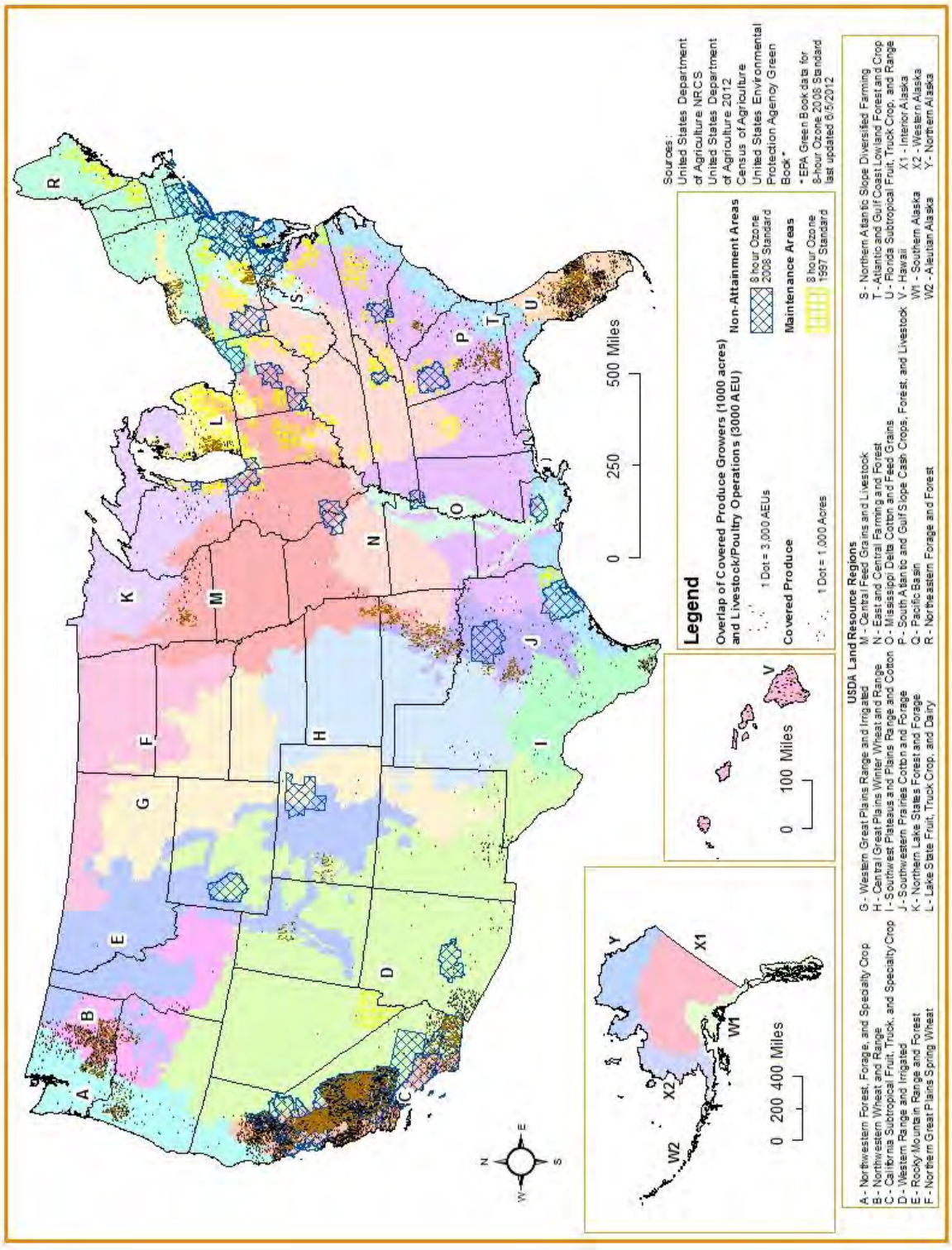
Ground-Level Ozone

Ozone (O_3) occurs in the upper atmosphere, where it shields the Earth from harmful ultraviolet radiation. However, at ground-level ozone acts as an air pollutant and is a main component of urban smog (EPA, 2012c). Ground-level ozone is not directly emitted into the air, but forms through chemical reactions of other pollutants (NO_x and VOCs) in the presence of sunlight. The concentrations of ground-level ozone and other related pollutants tend to be short-lived and spatially variable due to their high reactivity. Ozone concentrations tend to be at their highest on hot sunny days in urban areas, but can also be elevated in rural locations when O_3 is transported long distances by wind (EPA, 2012c). The main sources of NOx formation include soil microbial activity, lightning, biomass burning, and fuel combustion. The major sources of VOC emissions include transportation and industrial processes (EPA, 2012c).

Although they are typically not the primary sources of NO_x and VOCs, emissions of these O_3 precursor gases can result from a variety of agricultural practices and processes, such as manure decomposition, soil processes (nitrification/denitrification), and combustion from farm equipment. In addition to human health impacts, ground-level O_3 can lead to adverse effects on plants and animals and has been documented in contributing to reductions in crop yields by negatively impacting the photosynthetic ability of plants (USDA NRCS, 2012b).

Figure 3.5-7 shows the O_3 non-attainment areas based on the current 2008 standard and the maintenance areas associated with the older 1997 standard. These maintenance areas were designated non-attainment under the 1997 standard but have since demonstrated improvements in air quality related to O_3 and are currently in attainment based on the stricter 2008 standard (EPA, 2014j). This map illustrates that, similarly to particulate matter pollution, the majority of the non-attainment areas that coincide with large concentrations of covered farms and livestock operations are located in central and southern California (regions C and D).

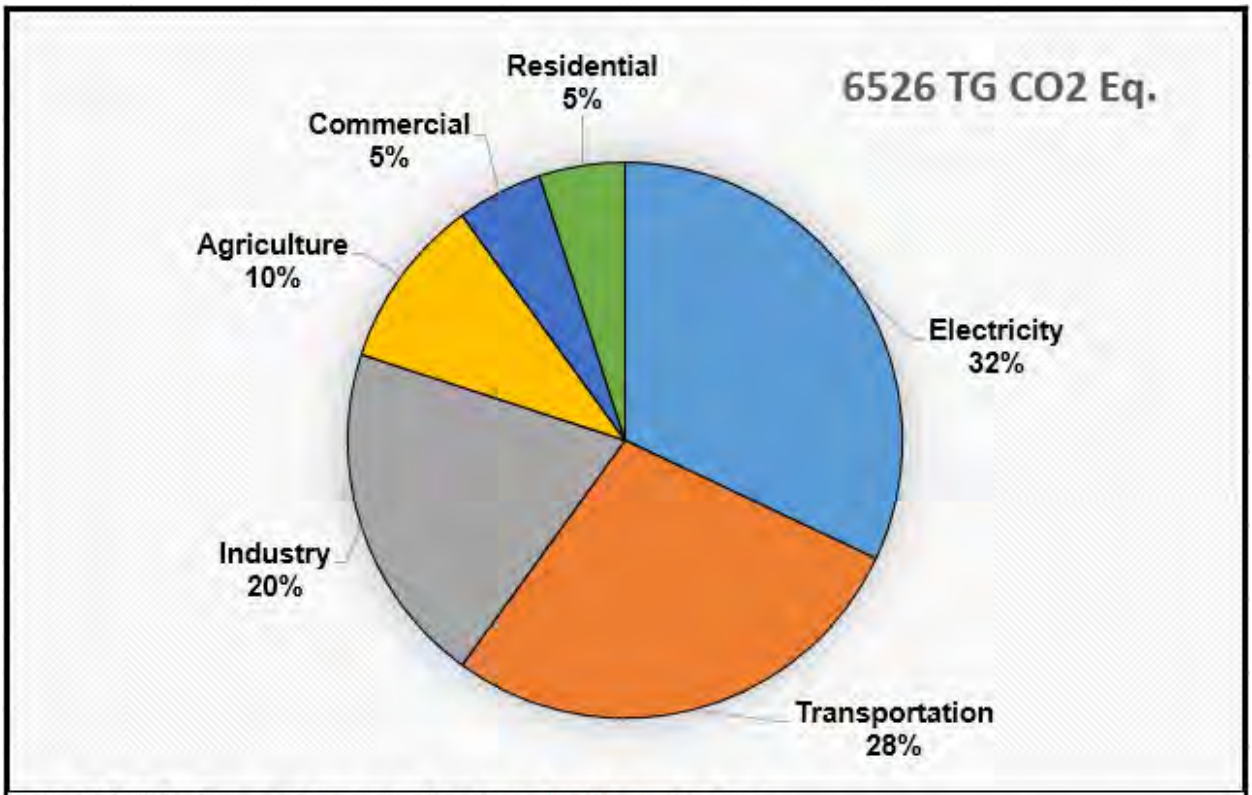
Figure 3.5-7. Ozone Non-Attainment Areas (2008 Standard) and Maintenance Areas (from 1997 Standard) (EPA, 2014j)



Existing Conditions Summary: Major GHSs

Human activities are responsible for a large proportion of the increase in GHGs seen in the atmosphere over the last 150 years. The largest source of anthropogenic greenhouse gas emissions in the U.S. comes from the burning of fossil fuels for electricity, heat, and transportation. Agricultural activities contribute directly to emissions of GHGs through a variety of processes, such as enteric fermentation in domestic livestock, livestock manure management, rice cultivation, agricultural soil management, land use changes, fuel consumption, and field burning of agricultural residues. In 2012, agricultural GHG sources accounted for approximately 10 percent of total U.S. GHG emissions (Figure 3.5-8) (EPA, 2014k). Agricultural activities may serve as sources of GHG emissions or as sinks through carbon sequestration (Table 3.5-1). National policies with regard to greenhouse gas emissions are currently limited, and agriculture has been largely excluded from regulatory and legislative proposals (Copeland, 2014).

Figure 3.5-8. U.S. Greenhouse gas emissions by economic sector, 2012 (EPA, 2014k)



Note: TG CO_2 Eq. = teragrams of carbon dioxide equivalents.

Source: EPA, Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2012, Table ES-7

Table 3.5-1. Agricultural Sector Greenhouse Gas Emissions and Sinks, 2012 (EPA, 2014k)

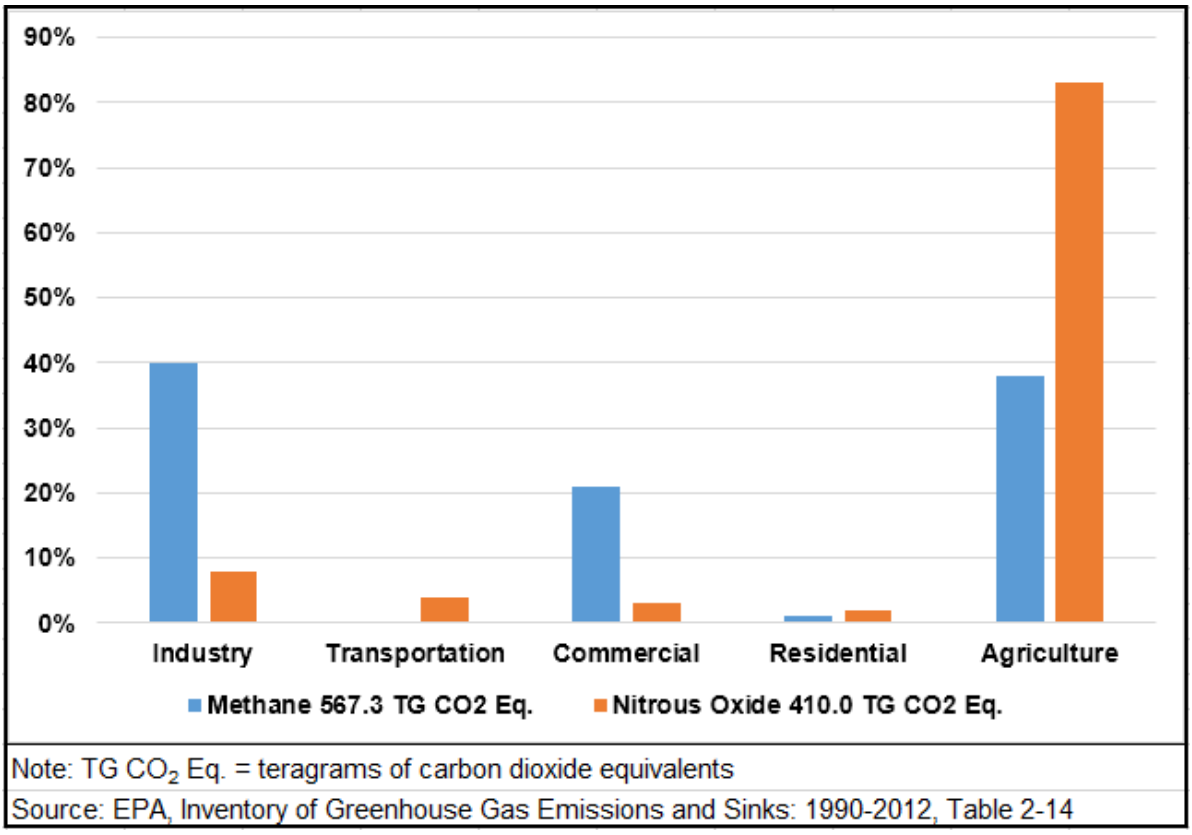
GHG Emissions Source	Tg CO_2 Eq.	Carbon Sink	Tg CO_2 Eq.
Agricultural Soil Management	306.6	Forest Land Remaining Forest	-866.5
Enteric Fermentation	141.0	Settlements Remaining Settlements	-88.4
Manure Management	70.9	Cropland Remaining Cropland	-26.5
Land Converted to Cropland	16.8	Land Converted to Grassland	-8.5
Rice Cultivation	7.4		
Grassland Remaining Grassland	6.7		
Agricultural Equipment	0.6		
Burning of Ag. Residues	0.4		

Source: EPA, Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2012 (April 2014), Tables 6-1, 7-1, 3-13, and 3-14

Fossil fuel combustion is the primary source of anthropogenic CO_2 emissions, with forest clearing, biomass burning, and some non-energy production processes also causing emissions (EPA, 2014k). Although CO_2 accounts for over 80 percent of U.S. GHG emissions, methane and nitrous oxide are the primary GHGs emitted by agricultural activities (USDA CCPO, 2011). Despite being less abundant than CO_2, the more efficient trapping of radiation by methane and the long duration time of nitrous oxide in the atmosphere makes small quantities of these compounds have significant effects on climate change. To address this, the Intergovernmental Panel on Climate Change (IPCC) developed the Global Warming Potential (GWP) concept to compare the ability of a gas to trap heat in the atmosphere relative to CO_2. For example, the comparative climate impacts of one pound of CH_4 or N_2O are approximately 21 and 310 times greater, respectively, relative to one pound of atmospheric CO_2. Estimates of GHG emissions can then be weighted by the GWP to produce a standardized measurement, such as teragrams of carbon dioxide equivalent, or Tg CO_2 Eq. (EPA, 2014k).

Agriculture made up 38 percent of total U.S. CH_4 emissions in 2012 and 83 percent of total N_2O emissions (EPA, 2014k, see Figure 3.5-9). Between 1990 and 2012, methane emissions from agricultural activities increased by 13.6 percent, while N_2O emissions had an overall increase of 9.5 percent. The primary GHG sources for agriculture are N_2O emissions from cropped and grazed soils, CH_4 emissions from ruminant livestock production and rice cultivation, and CH_4 and N_2O emissions from managed livestock waste. Agricultural soil activities such as fertilizer application produced approximately 74.8 percent of N_2O emissions in the U.S. in 2012. Enteric fermentation was the largest source of CH_4 emissions in the U.S. in 2012, at 141.0 Tg CO_2 Eq. Overall, emissions from manure management (includes CH_4 and N_2O) increased 54.7 percent between 1990 and 2012 (EPA, 2014k).

Figure 3.5-9. U.S. Methane and Nitrous Oxide Emissions by Sector in 2012 (EPA, 2014k)



Note: TG CO_2 Eq. = teragrams of carbon dioxide equivalents

Source: EPA, Inventory of Greenhouse Gas Emissions and Sinks: 1990-2012, Table 2-14

Agricultural soil management and manure management are the two largest direct sources of agricultural greenhouse gas emissions most likely to be affected by the PS PR, particularly with regard to standards directed at BSAs of animal origin. Figure 3.5-10 shows the total N_2O emissions by state (note: data unavailable for Alaska) from agricultural soil management (including croplands and grasslands) in 2012, which are highest in areas of intensive agriculture such as Texas, California, and most upper mid-western states (EPA, 2014k). Figure 3.5-11 illustrates the total GHG emissions (CH_4 and N_2O combined) by state from manure management in 2012 (EPA, 2014k). Approximately 51 percent of these emissions can be attributed to just six states (California, Iowa, Texas, North Carolina, Wisconsin, and Minnesota).

According to a 2011 USDA study, crop production (mostly from non-rice soils) contributed close to one third (31 percent) of total GHG emissions from agricultural sources in 2008. The production of livestock represented the majority of total emissions from the agricultural sector, with 28 percent from enteric fermentation, 12 percent from managed livestock waste, and 13 percent from grazed lands. Finally, 14 percent of total emissions were a result of energy use for agricultural activities (USDA CCPO, 2011).

Figure 3.5-10. Total nitrous oxide (N_2O) emissions from agricultural soil management by state in 2012, including emissions from croplands and grasslands (EPA, 2014k)

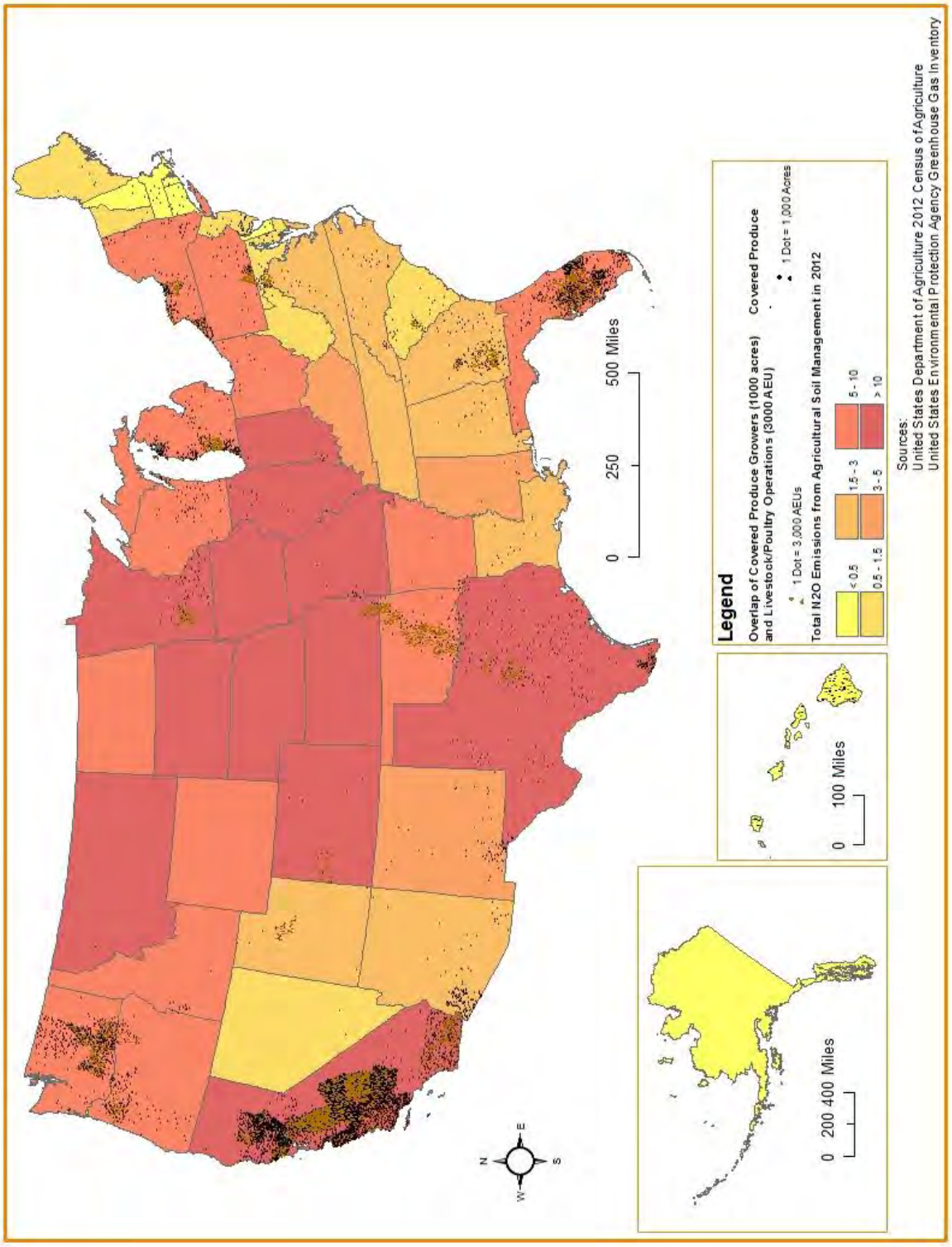
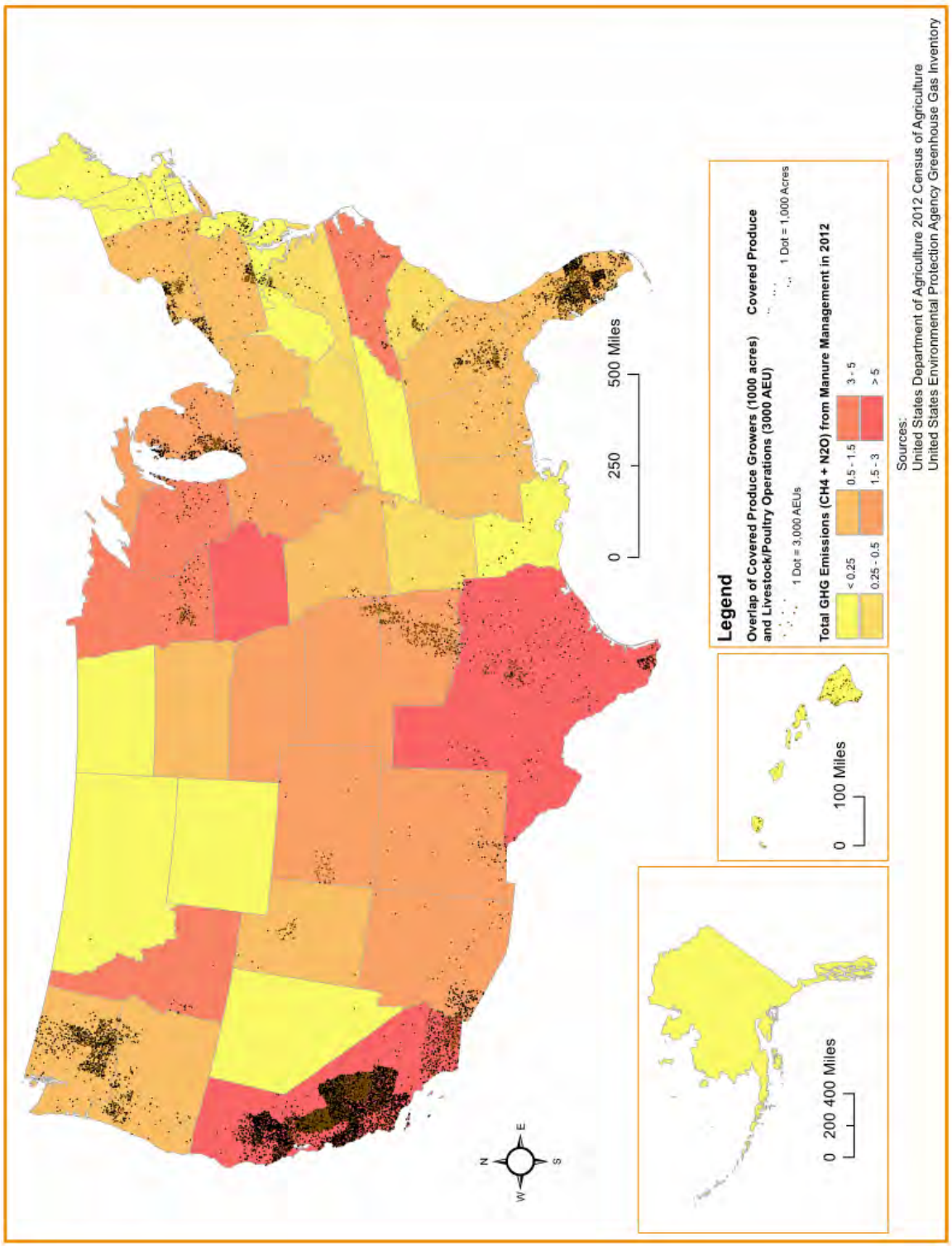


Figure 3.5-11. Total GHG Emissions from manure management by state in 2012, including methane (CH_4) and nitrous oxide (N_2O) emissions (EPA, 2014k)

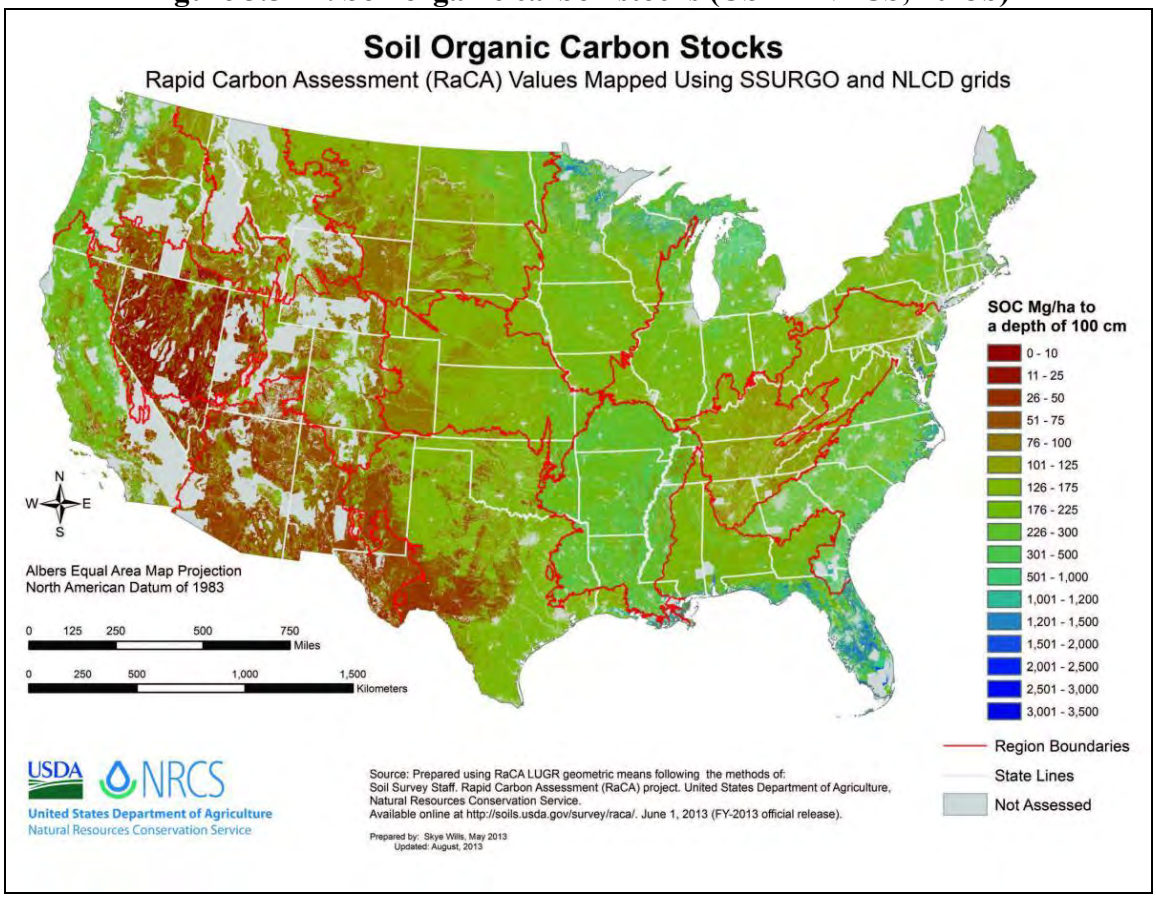


Carbon Sequestration

Soils make up a major part of the global carbon cycle (Figure 3.5-12). Soils have added as much as 55 to 878 billion tons (GT) of carbon to the total atmospheric CO_2. The total soil carbon consists of the SOC and inorganic carbon, estimated to be over 2,250 GT in the top 1 meter depth (Batjes, 1996). The SOC consists of "a mixture of plant and animal residues at various stages of decomposition, of substances synthesized microbiologically and or chemically from the breakdown products, and of the bodies of live microorganisms and small animals." The SOC includes elemental carbon and carbonates (Li and Feng, 2002).

Although carbon emissions from agricultural activities contribute the enrichment of atmospheric CO_2, carbon sequestration in agricultural soils, through the use of proper management practices, can mitigate this trend. While the soil inorganic carbon contributes approximately 25 percent of the overall soil carbon inventory, agricultural activities have a more profound influence on changes of SOC both in the short and the long term. Increasing SOC content enhances soil quality, reduces soil erosion and degradation, improves surface water quality, and increases soil productivity. Thus, carbon sequestration in soils, (i.e., increasing SOC in agricultural soils through proper management), provides a multitude of environmental benefits. The goals to sequester SOC is to create a win-win situation to improve soil productivity, reduce unnecessary inputs, and promote sustainability (Li and Feng, 2002).

Figure 3.5-12. Soil organic carbon stocks (USDA NRCS, 2013b)



Energy use in agriculture

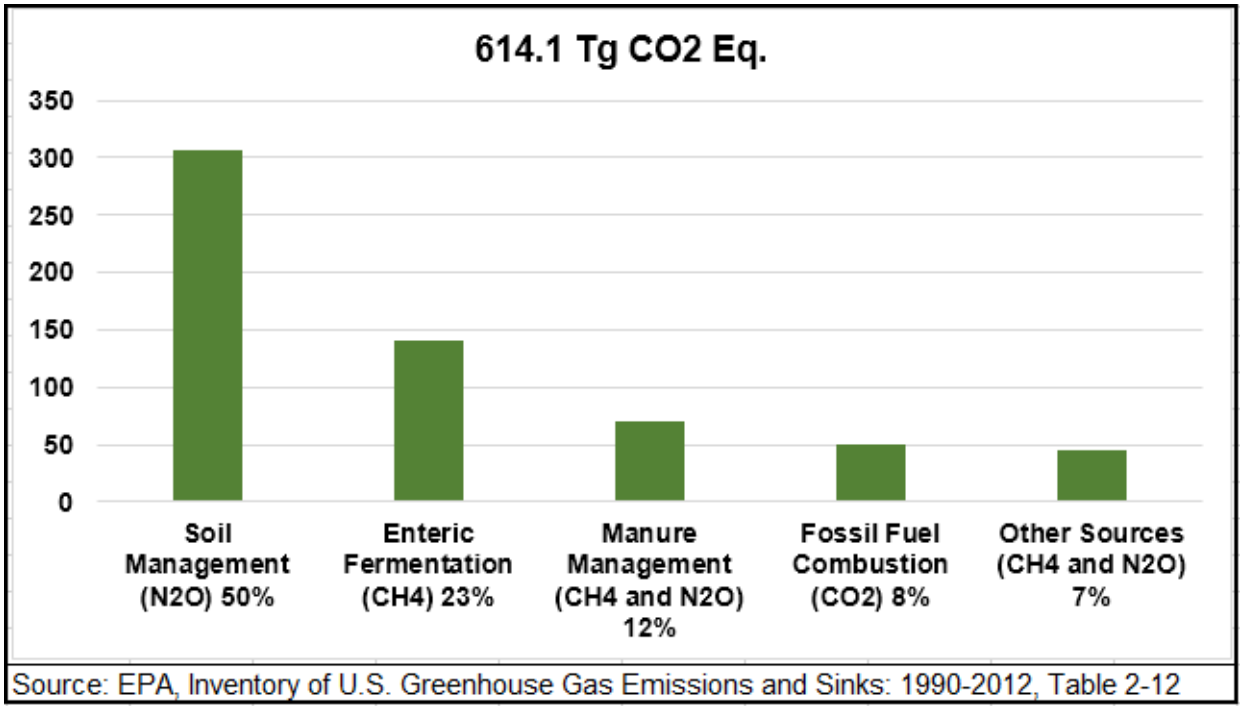
Farm operators rely on a variety of energy sources to perform agricultural practices. How energy is used in agriculture is impacted by many factors including the type of crop or livestock being produced, the size of the farm, and the geographic location. Additionally, temporal variation in energy use can result from changes in weather conditions, energy prices, and total annual production of crops and livestock. Although agricultural energy use does contribute to CO_2 emissions, this source is small relative to the total U.S. CO_2 emissions from energy (USDA CCPO, 2011). Energy use represented approximately 8 percent of the total GHG emissions from the agricultural sector in 2012 (Figure 3.5-13) (EPA, 2014k).

Approximately 0.8 quadrillion btu (British thermal unit) of direct energy was used in agriculture in 2008, resulting in approximately 72 Tg CO_2 Eq. emissions, mostly from electricity use and diesel fuel use (38 percent each) (USDA CCPO, 2011). Energy use for agricultural practices can be categorized as direct or indirect. Direct energy is used for farm operations involved in crop or livestock production, while indirect energy is used to produce synthetic fertilizers and other inputs. Large amounts of diesel fuel, gasoline, and liquefied petroleum (LP) gas are used for field operations during crop production. Most large farms use diesel-fueled vehicles to perform agricultural practices. Gasoline-powered vehicles and equipment, which can include small trucks or older harvesting equipment, tend to be used on smaller farms. The amount and type of energy used in agricultural operations affect overall CO_2 emissions through differences in carbon content and energy efficiency. For example, diesel fuel has a higher carbon content compared to gasoline, but diesel engines are more energy efficient and may still result in lower CO_2 emissions (USDA CCPO, 2011).

Irrigation systems that use pumps to distribute water also use energy. In 2008, approximately 49 million acres of U.S. farmland were irrigated with pumps powered by liquid fuels, natural gas, and electricity (USDA CCPO, 2011). Electricity was the main power source for these pumps, costing $1.5 billion to irrigate about 30 million acres. Diesel fuel was used to power pumps on about 13 million acres and natural gas was used on about 4.7 million acres (USDA NASS, 2009e).

Source categories of emissions from electricity generation include CO_2 from fossil fuel combustion, CO_2 and N_2O emissions from the incineration of waste, and CH_4 and N_2O from stationary sources. Although electricity generation is often analyzed as a major source of GHG emissions, electricity is ultimately consumed in different economic sectors. Electricity-related GHG emissions are mostly distributed among the industrial, transportation, commercial, and residential economic sectors. According to the EPA, in 2012 electricity-related emissions were responsible for approximately 62.2 Tg CO_2 Eq. of the 676.3 Tg CO_2 Eq. total GHG emissions from the agricultural sector. This represents only three percent of the total GHG emissions attributed to the electric power industry in 2012 (EPA, 2014k).

Figure 3.5-13. Greenhouse gas emissions from agriculture by source, 2012 (EPA, 2014k)



Nitrous Oxide Emissions

Nitrous oxide emissions can result from a variety of anthropogenic sources including agricultural soils, the use of synthetic and manure fertilizers, manure deposition by livestock, fossil fuel combustion, wastewater treatment, waste incineration, and biomass burning. The agricultural sector is the biggest producer of N_2O emissions in the U.S. (Figure 3.5-13). Agricultural soils accounted for approximately 74.8 percent (306.6 Tg CO_2 Eq.) of U.S. N_2O emissions in 2012 (EPA, 2014k). A major contributor to these emissions is the addition of large amounts of nitrogen fertilizers to crops that stimulates the production and direct emission of N_2O (USDA CCPO, 2011). Nitrous oxide emissions can also occur during indirect processes such as the conversion of nitrates in groundwater into N_2O by aquatic denitrification. In 2008, 80 percent of total cropland soil N_2O emissions were direct soil emissions and 20 percent were indirect emissions from nitrate leaching and volatilization (USDA CCPO, 2011).

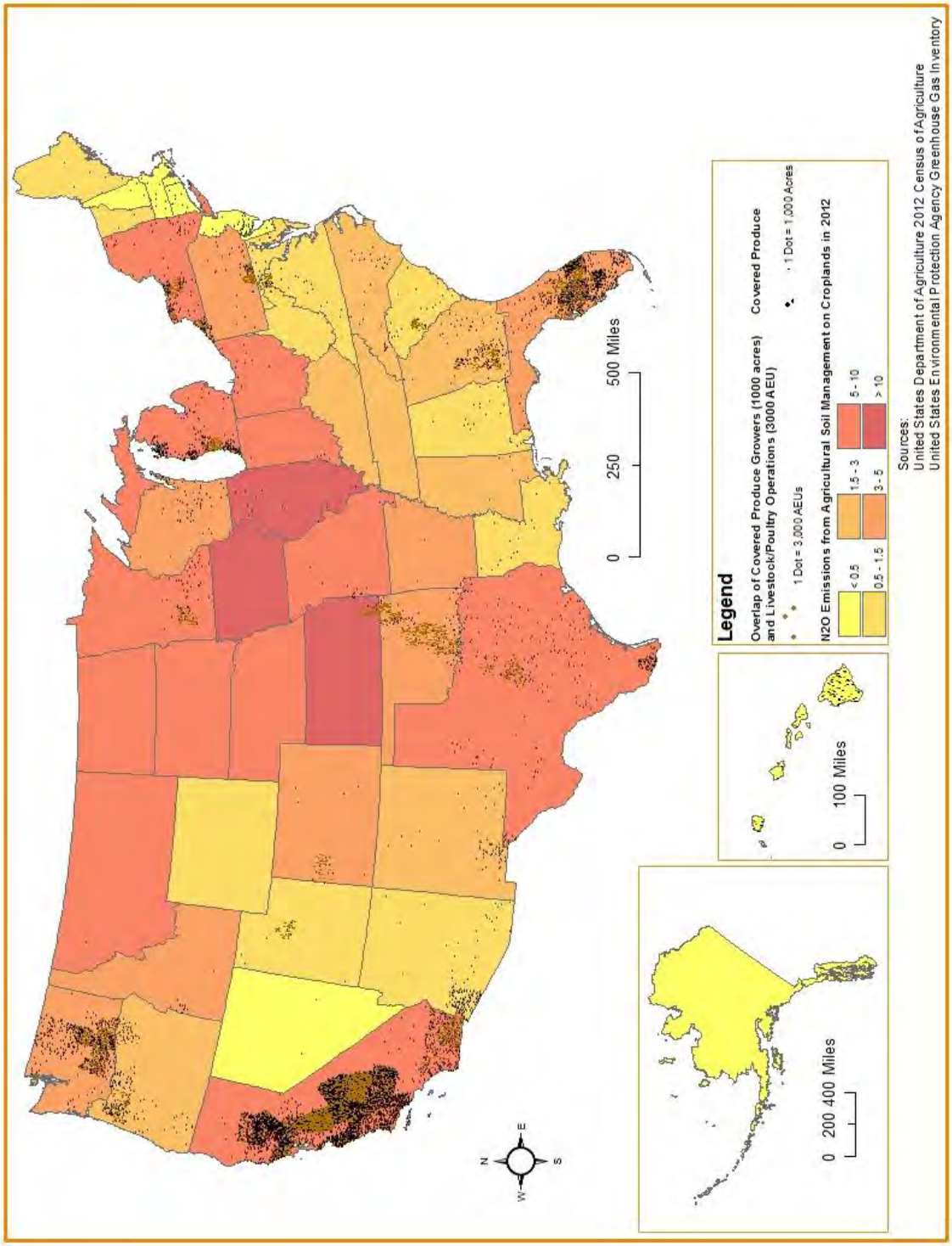
Nitrous oxide is produced naturally in soils through the microbial processes of nitrification and denitrification. Many agricultural activities increase mineral nitrogen availability in soils, ultimately increasing the amount of N_2O emitted. These practices may include fertilization, application of managed livestock manure, production of nitrogen-fixing crops, retention of crop residues, and drainage of organic soils in croplands and grasslands. Nitrous oxide emissions can also be impacted by other agricultural soil management activities such as irrigation, drainage, tillage practices, and fallowing of land (EPA, 2014k). When more nitrogen is applied than can be

used by the plants, either due to the volume or timing of application of manure or fertilizer, the rate of N_2O emissions is increased (USDA CCPO, 2011).

Nitrous oxide emissions from manure management can occur directly through the nitrification and denitrification of the organic nitrogen in livestock waste, and indirectly through volatilization or the leaching and runoff of nitrogen into groundwater and surface waters (EPA, 2014k). Nitrous oxide emissions from manure management are most likely to occur in dry manure handling systems with aerobic conditions that also contain saturated pockets with anaerobic conditions because both types of reactions are required for direct N_2O emissions to occur. Liquid manure storage systems, which are becoming more prevalent in some industries, can also lead to increased volatilization of nitrogen that can escape into the air (Copeland, 2014). In 2012, total N_2O emissions from manure management were estimated at 18.0 Tg CO_2 Eq., an increase of 3.6 Tg CO_2 Eq. over emissions in 1990 (EPA, 2014k).

On average, cropland accounted for approximately 61 percent of total direct N_2O emissions in 2012, while grassland accounted for approximately 39 percent (EPA, 2014k). Nitrous oxide emissions are highly correlated with crop areas and nitrogen inputs. The highest concentrations of N_2O emissions occur in areas of the U.S. where a large portion of land is used for intensive agriculture. Notably, over 90 percent of the land in many counties in the Midwest is intensively cropped. The leading crops for nitrous oxide emissions are corn, soybeans, and hay, largely due to the land area represented by these crops (USDA CCPO, 2011). Direct N_2O emissions tend to be low in the eastern U.S. where a small portion of land is cultivated, and also low in many western areas where rainfall and access to irrigation water are limited (EPA, 2014k). Figure 3.5-14 illustrates the nitrous oxide emissions by state (note: data unavailable for Alaska) from agricultural soil management on croplands in 2012 (EPA, 2014k), over 60 percent of which can be attributed to most upper and central mid-western states, Texas, and California. Direct emissions from grasslands are highest in the central and western U.S. where a high proportion of land features cattle grazing (EPA, 2014k). Non-major crop types resulted in approximately 17 percent of the total N_2O emissions from croplands in 2008. Note that non-major crops (e.g., fruits and vegetables) make up a significant portion of total emissions in some states including California and Florida (USDA CCPO, 2011).

Figure 3.5-14. Nitrous oxide (N_2O) emissions from agricultural soil management on croplands by state in 2012 (EPA, 2014k)



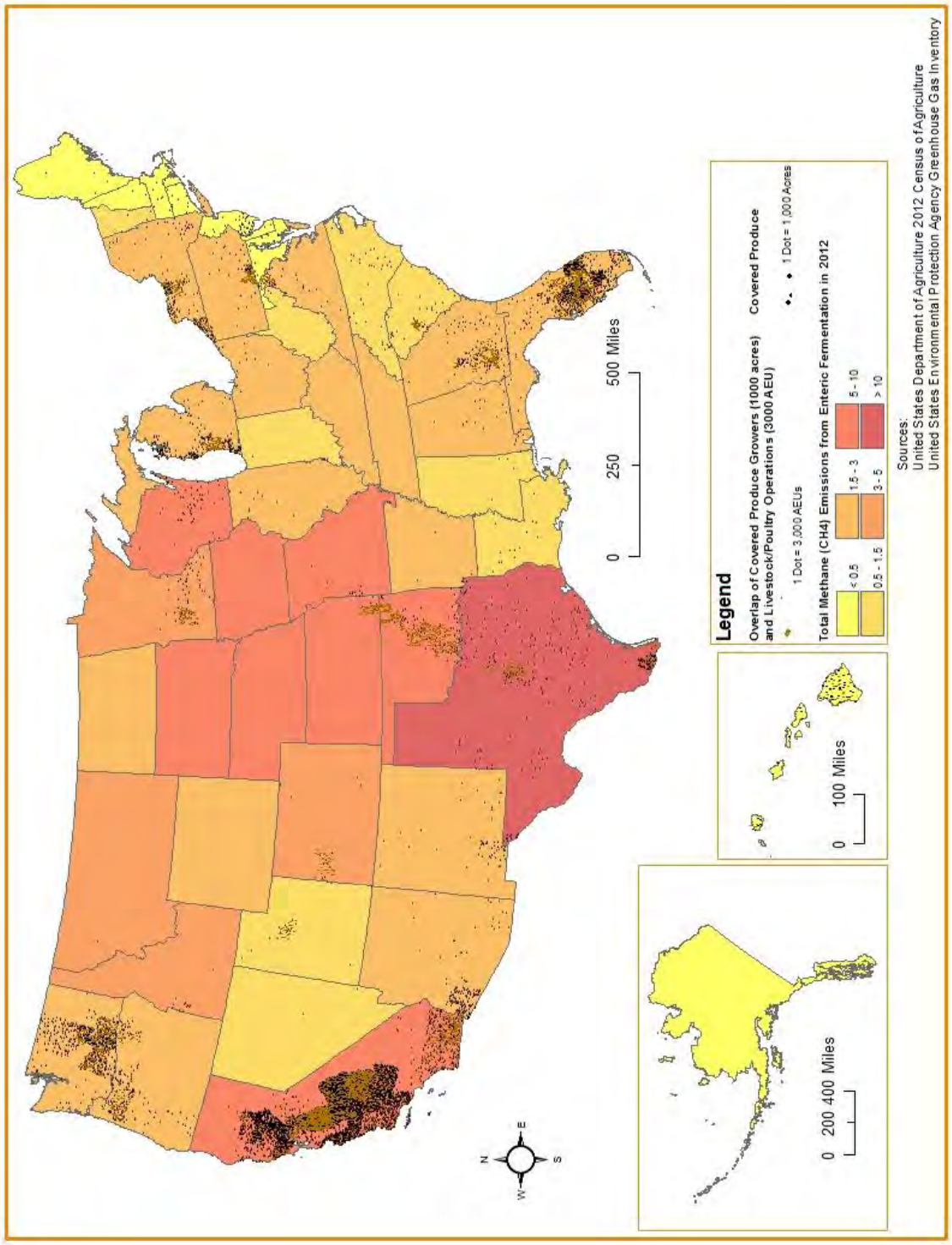
Methane Emissions

Methane is primarily produced through the anaerobic decomposition of organic matter in biological systems. Agricultural processes such as enteric fermentation in animals, decomposition of animal wastes, and wetland rice cultivation are all sources of CH_4 emissions. The decomposition of municipal solid wastes and the production and distribution of some fossil fuels can also result in CH_4 emissions (EPA, 2014k). The IPCC has estimated that slightly more than half of the current CH_4 flux to the atmosphere can be tied to anthropogenic sources (Forster et al., 2007).

Methane is produced as part of normal digestive processes in animals and the microbial fermentation process involved is referred to as enteric fermentation, which represents the largest anthropogenic source of methane emissions in the U.S. Ruminant animals (e.g., cattle, sheep, and goats) are the major emitters of methane due to their unique digestive system, which includes a rumen in which food is broken down by microbial fermentation. Non-ruminant animals (e.g., swine, horses, mules) also contribute to CH_4 emissions but at a much lower rate relative to ruminant livestock. Total livestock methane emissions in 2012 were 141.0 Tg CO_2 Eq. (approximately 25 percent of total CH_4 emissions), with cattle (beef and dairy combined) accounting for 96 percent of these emissions (EPA, 2014k). Not surprisingly, changes in enteric fermentation emissions over time generally follow trends in cattle population sizes.

Figure 3.5-15 illustrates the total CH_4 emissions by state from enteric fermentation in 2012 (EPA, 2014k). Approximately half of the total CH_4 emissions from enteric fermentation in 2012 can be attributed to livestock operations in nine states, including several mid-western states as well as California. It is unlikely that the provisions of the PS PR will cause direct CH_4 emissions from enteric fermentation to change dramatically, as compliance from farmers will relate more to storage and application of manure than to emissions from animal digestion itself. However, Figure 3.5-15 does show which states are dominated by cattle production relative to where concentrations of covered farms are located.

Figure 3.5-15. Total methane (CH_4) emissions from enteric fermentation by state in 2012 (EPA, 2014k)



The treatment, storage, and transportation of livestock manure can produce anthropogenic CH_4 emissions through the anaerobic decomposition of the manure. Methane emissions from manure management have increased by roughly 68 percent since 1990, from 31.5 Tg CO_2 Eq. in 1990 to 52.9 Tg CO_2 Eq. in 2012 (EPA, 2014k). When manure is stored or treated in systems that promote anaerobic conditions (e.g., liquid slurry in tanks, ponds), the decomposition process tends to produce CH_4. Production is greatly reduced when manure is handled as a solid (e.g., in stacks or drylots) or deposited on pasture lands and allowed to decompose aerobically. Overall, land application has been and remains the predominant method for disposing of manure and recycling its nutrient and organic content. For the most part, design objectives for managing manure have focused on odor and dust control, avoidance of direct discharge to surface water, and land application rates to maximize crop yields, largely ignoring minimization of gaseous compounds such as CH_4 (Copeland, 2014).

The majority of managed manure in the U.S. is currently handled as a solid, contributing little CH_4 to overall emissions. However, liquid systems of manure management are becoming more common, particularly in dairy and swine operations. Dairy animal populations have been decreasing overall since 1990. However, dairy populations have increased in some states such as California and New Mexico due to the industry becoming more concentrated with larger facilities, which all tend to use liquid manure systems to manage livestock waste. Manure management practices at smaller operations are also shifting from daily spread to manure managed and stored on site due to new regulations limiting the application of manure nutrients (EPA, 2014k). Livestock waste is termed "unmanaged" when it is deposited directly on grazed lands and not transported (USDA CCPO, 2011).

Agriculture, Air Quality, and the PS PR

The following section briefly discusses how agricultural operations and air quality resources relate to each of the major standards of the PS PR. These discussions are expanded upon in Chapter 4 (Environmental Consequences). This section also lists the types of pollutants that are expected to be impacted by each of the standards in the PS PR.

- **Agricultural Water Standards:** Agricultural water standards can relate to chemical treatments of agricultural water as well as energy use with regard to water systems (e.g., groundwater pumps). Emissions of CO_2 and criteria air pollutants can result from direct fuel combustion or electricity generation involved in running pumps or other water-transport systems during agricultural operations. In addition, chemical treatments of agricultural water to address pathogens can cause emissions of VOCs.

- **Biological Soil Amendment (BSA) Standards:** Standards directed towards BSAs of animal origin (both untreated and treated) represent the largest potential source of impacts to air quality and GHGs related to the PS PR. The use of BSAs of animal origin (and other soil amendments) primarily involves effects associated with manure management and agricultural soil management practices. The need for storage of greater amounts of manure expected under the standards of the PS PR could result in increases in emissions of windborne PM, O_3 precursor gases, and GHGs (primarily CH_4 but also

N_2O). Changes in agricultural soil management could occur if growers were to switch to other soil amendments. In particular, the greater use of chemical fertilizers could result in increases in N_2O emissions if greater amounts of nitrogen are available in the soil. Finally, any increase in transportation of manure to on or off-site storage or composting facilities could cause increases in emissions of CO_2 and criteria pollutants from fuel combustion, although changes in emissions would be relatively low since trucking of manure would likely occur in localized areas due to economic feasibility.

- **Grazing and Animal Intrusion Standards:** Emissions of PM and major GHGs can occur on grazed lands due to agricultural soil management activities and processes, as well as from animal activities (e.g., enteric fermentation, manure decomposition). However, the standards directed towards grazing and animal intrusion from wild and domesticated animals are not anticipated to have major effects on air quality resources, as overall manure management and agricultural soil management practices would be expected to remain intact. Actions taken by growers to remove or exclude animals from covered produce fields could result in PM and VOC emissions (e.g., switching to chemical pesticides), or emissions of PM and CH_4 from manure being concentrated in certain areas.

- **Sprouts Standards:** The relationship of standards directed towards sprouts to air quality resources is similar to that of agricultural water in general. Emissions of CO_2 and criteria air pollutants can result from direct fuel combustion or electricity generation involved in running pumps or other water-transport systems during agricultural operations. In addition, chemical treatments of agricultural water to address pathogens can cause emissions of VOCs.

- **Scope of the Rule (Businesses Covered):** The overall impacts to air quality resources with regard to the PS PR will result from the combined effects of growers' actions to address the various standards. It is anticipated that these actions will result in larger air quality effects on large farms relative to Small and Very Small farms.

Summary of Impact Assessment Methodology

In the U.S., air quality research in the past half-century has focused largely on NO_x, SO_2, O_3, and PM emissions from the industrial, transportation, and energy sectors (Aneja et al., 2009). There are currently no nationwide monitoring networks in the U.S. to quantify agricultural emissions of GHGs, NO_x, VOCs, or NH_3. Conversely, there is a large network in place to assess atmospheric changes resulting from fossil fuel combustion. Furthermore, researchers have noted large uncertainties in current agricultural air quality modeling as a result of many factors including (1) inaccurate emission inventories; (2) inaccurate meteorological data; (3) lack of detailed information on land use at a fine scale; (4) inadequate model treatments of chemical and physical processes; and (5) a lack of sufficient observations of emissions, concentrations, and deposition for model verification and evaluation (Aneja et al., 2009).

For the alternatives of the major provisions of the PS PR (discussed in depth in Chapter 4), FDA addressed impacts on air quality and GHGs using a primarily qualitative assessment on a

national scale. In addition, FDA used a regional approach because it is apparent that covered farms and associated livestock operations are heavily concentrated in certain areas (see Figure 3.5-2). Specifically, considerations of impacts to air quality focused on a combination of two major sources:

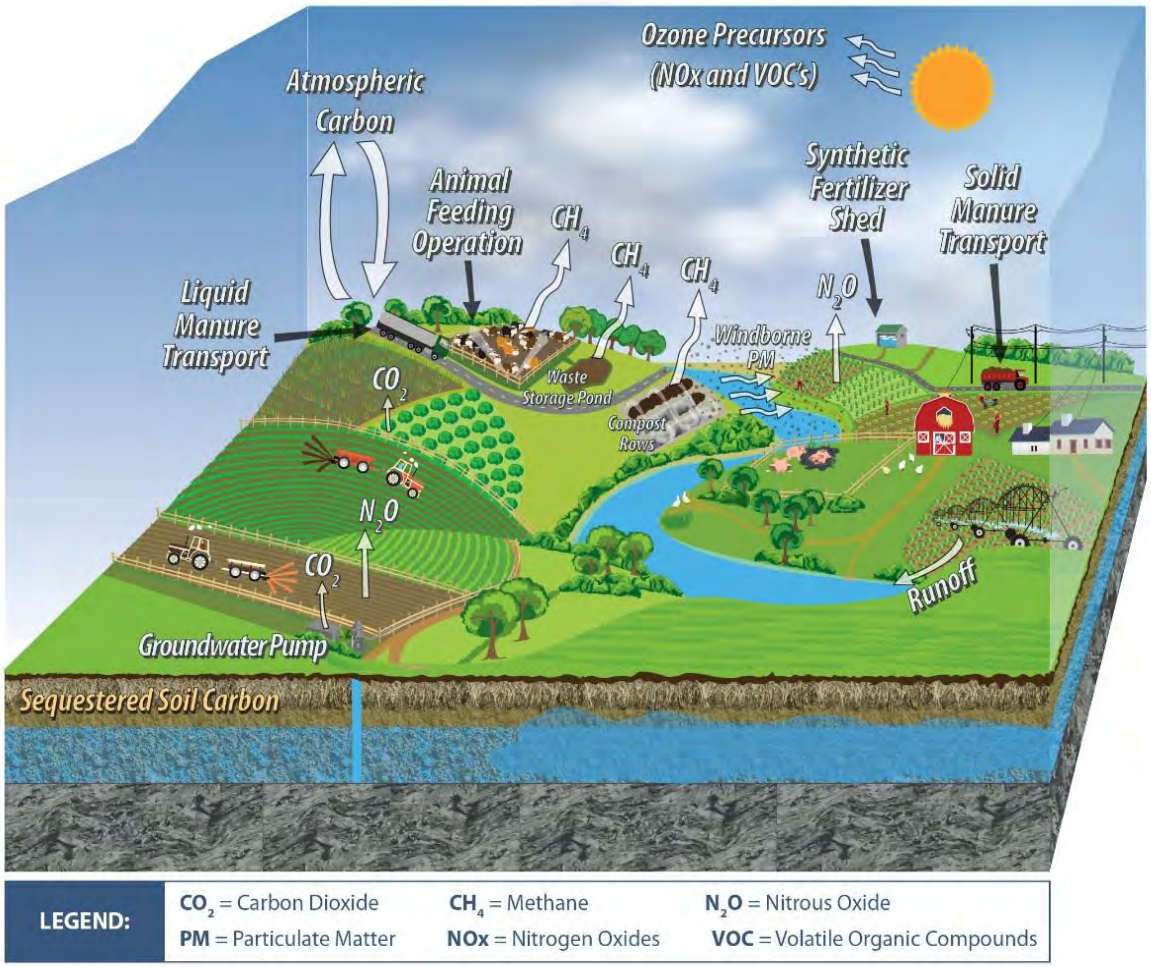
1) Is the proposed alternative likely to cause or contribute to violations of National Ambient Air Quality Standards (NAAQS) of criteria pollutants?
2) Is the proposed alternative likely to cause increases in major greenhouse gas emissions (CO_2, N_2O, and CH_4)?

Data and maps presented in this chapter, such as existing non-attainment areas for criteria air pollutants and state-level emissions of major GHGs, are referenced to support the major conclusions. However, FDA could not conduct a detailed quantitative analysis estimating changes in emissions due to a lack of sufficient data regarding emissions of air pollutants and GHGs from agricultural operations, specifically covered farms (Copeland, 2014). In particular, specific information on existing emissions from agricultural soil management and manure management activities from covered farms were lacking. Additionally, data on agricultural emissions of particulate matter typically focus on crop/livestock dust and livestock waste sources. Other major sources of PM emissions, such as un-paved road dust, are categorized separately by EPA and are not classified by source sector (e.g., agricultural operations). Finally, accurate estimates of changes in CO_2 emissions would require data on expected changes in vehicle-miles traveled (due to increased storage and disposal of manure) and energy use (e.g., groundwater pumps).

In 2014, CEQ issued *Revised Draft Guidance for Greenhouse Gas Emissions and Climate Change Impacts* (CEQ, 2014b), which recommends that any proposed actions that would not be reasonably anticipated to cause direct annual emissions of 25,000 metric tons or more of CO_2 Equivalent (CO_2 Eq.) GHG emissions are not recommended for a quantitative assessment. This indicator is not proposed to be used as a threshold of significant impacts, but rather as a minimum amount of emissions for moving forward with detailed analyses (CEQ, 2014b). It is noted that this indicator has been used in rule makings under the CAA, such as EPA's Mandatory Reporting of Greenhouse Gases Final Rule (74 Fed. Reg. 56260, October 30, 2009); however, this rule primarily relates to large stationary emitters (e.g., power plants) and has not been regularly applied to agricultural operations (Copeland, 2014). Although indicator-levels of emissions (such as 25,000 metric tons of CO_2 Eq.) may be useful in impact assessment, they could not be adequately applied for the PS PR due to a lack of data required for estimating changes in emissions. Figure 3.5-16 illustrates many of the major operations, activities, and processes that contribute to emissions of criteria pollutants and GHGs on working produce farms that may be affected by the PS PR. This graphic summarizes information described within the Air Quality Affected Environment section and includes croplands and livestock operations in order to most comprehensively represent the types of activities that may be affected by the various provisions of the PS PR. This figure is referred to for illustrative purposes when discussing potential Air Quality impacts in Chapter 4. The following provides a summary of the major air pollutants and the agricultural activities associated with their emissions that are depicted in Figure 3.5-16:

- **Carbon Sequestration:** Carbon can be sequestered in both soils and living plants, which can help mitigate greenhouse gas emissions that end up in the atmospheric carbon pool (Li and Feng, 2002).
- **Methane (CH_4) Emissions:** Enteric fermentation of livestock, such as those in AFOs, is the leading agricultural source of CH_4 emissions. Manure management also results in a significant amount of methane emissions to the atmosphere, both in liquid (e.g., waste storage pond) and solid (e.g., compost rows) management systems (EPA, 2014k).
- **Nitrous oxide (N_2O) Emissions:** Agricultural soil management, which includes the application of manure or synthetic fertilizers to croplands, is the single largest contributor of N_2O emissions in the United States. Manure management processes can also result in releases of nitrous oxide (EPA, 2014k).
- **Ozone (O_3) Formation:** Ozone can form when ozone-precursor gases such NO_x and VOCs react with sunlight. Although they are typically not the primary sources of NO_x and VOCs, emissions of these ozone precursor gases can result from a variety of agricultural practices and processes, such as manure decomposition, soil processes (nitrification/denitrification), and combustion from farm equipment (EPA, 2012c).
- **Particulate Matter (PM) Emissions:** Particulate matter emissions can result from a variety of sources such as vehicle traffic on unpaved roads, field operations (e.g., tractors), animal activity in open lots, and wind erosion of manure or compost piles. In addition, emissions of compounds such as NH_3 from animal activity and manure decomposition can contribute to PM formation (USDA NRCS, 2012a).
- **Energy Use:** Carbon dioxide (and other air pollutant) emissions can result from agricultural energy use from sources such as groundwater pumps, irrigation equipment, field operations (e.g., tractors spreading manure/fertilizer), and vehicles transporting manure on or off-site (USDA CCPO, 2011; EPA, 2014k).

Figure 3.5-16. Sources of emissions of air pollutants and GHGs on baseline working produce farm (crops and livestock operations)



3.6 Cultural Resources

3.6.1 Definition of the Resource

Cultural Resources

The Advisory Council on Historic Preservation (ACHP) defines *historic property* as "any prehistoric or historic district, site, building, structure, or object included in, or eligible for inclusion in, the National Register of Historic Places maintained by the Secretary of the Interior. This term includes artifacts, records, and remains that are related to and located within such properties. The term includes properties of traditional religious and cultural importance to an Indian tribe or Native Hawaiian organization and that meet the National Register criteria" (36 CFR § 800.16(l)(1)).

The PS PR primarily pertains to farms (defined by FDA in 79 Fed. Reg. 58434 at 58470-71) and in the glossary (Chapter 10) of this EIS.

Based on the definitions set forth above, with respect to farms, cultural resources are likely to include the historic farmstead (i.e., the farmhouse and associated domestic and agricultural outbuildings) as well as the agricultural lands that were historically associated with the farmstead. Generally, the cultural significance of farms is assessed based on the physical integrity of the farm (i.e., the built structures as well as the extant farmland), and the historical contributions the farms has made to agricultural production in the region.

3.6.2 Regulatory Oversight

Section 106 of the National Historic Preservation Act (NHPA) of 1966 as amended (16 U.S.C. § 470) mandates that federal agencies consider how their proposed project might have the potential to affect historic or cultural resources. Specifically, the NHPA as amended (16 U.S.C. § 470) states in Section 106:

> "The head of any Federal agency having direct or indirect jurisdiction over a proposed Federal or Federally assisted undertaking in any state and the head of any Federal department or independent agency having authority to license any undertaking shall, prior to the approval of the expenditure of any Federal funds on the undertaking or prior to the issuance of any license, as the case may be, take into account the effect of the undertaking on any district, site, building, structure, or object that is included in or eligible for inclusion in the National Register. The head of any such Federal agency shall afford the Advisory Council on Historic Preservation established under Title II of this Act a reasonable opportunity to comment with regard to such undertaking."

The regulations implementing NHPA, found in 36 CFR 800, states that federal agencies 1) determine whether activities proposed action constitute "undertakings" that have the potential to

cause effects on historic properties; and, 2) if so, to evaluate the effects of such undertakings on such historic resources and consult as appropriate (16 U.S.C. § 470f).

3.6.3 Current Background Conditions

While modifications may need to be made to farm productions in order to comply with the Rule, the PS PR does not constitute an "undertaking" in the scope of Section 106 of the NHPA as there is no expenditure of federal funds or issuance of any licenses for compliance such that modifications to potential historic resources on farms would be made by individual land owners in order to comply with the PS PR.

As there is no federal undertaking, Section 106 of the NHPA does not apply to the PS PR. No further evaluation or consideration of potential impacts on historic or cultural resources is necessary. Chapter 4, under the subheading for Resource components not included for review in the EIS, provides additional information on FDA's consideration of cultural resources with respect to EIS impact analysis.

3.7 Socioeconomics and Environmental Justice

3.7.1 Definition of the Resource

Socioeconomics

When an EIS is prepared and socioeconomic and natural or physical environmental effects are interrelated, the EIS must discuss the socioeconomic effects on the human environment. As defined within the CEQ Regulations for Implementing NEPA, the "human environment" comprehensively includes "the natural and physical environment and the relationship of people with that environment" (40 CFR 1508.14). For purposes of the socioeconomics section of this Final EIS, we considered the following factors: (1) direct or indirect effects interrelated with the environmental impacts of any alternative; (2) consistent with 40 CFR 1502.23, how economic impacts from the cost-benefit analysis might inform on any agency decision making (e.g., economic impacts considered in the proposed rule that would impact how we compare alternatives under 40 CFR 1502.23).

The socioeconomic section of this EIS describes the existing population and demographic trends, including income, employment, and housing conditions, that have been identified within the geographic scope of the EIS (Chapter 1.9). The resources discussed in the sections that follow include general agricultural characteristics associated with the number of farms, acres of primary field crops, and revenues generated from primary field crops, as well as an analysis of rural population trends. The resources identified are essential to the description of the high-level demographic and economic components of the national agricultural operator population and industry.

Socioeconomic information was obtained from the USDA Census, specifically the 2012 dataset (USDA NASS, 2014a). The USDA Census includes a comprehensive summary of agricultural activity, farm operations, and farm operators at the national, state, and county level for "any place from which $1,000 or more of agricultural products were produced and sold, or normally would have been sold, during the census year." To provide for regional comparisons, USDA Report Form Regions, as identified within the 2012 Census of Agriculture, are used in this analysis. Alaska and Hawaii are not included in the USDA's Report Form Regions; in an effort to include these states in the socioeconomic analysis, a new region has been created specifically for this resource component, the Non-Contiguous States Region, as noted in the analysis. This region, in Chapter 4, however, will be related to Alaska and Hawaii's appropriate produce region as identified in Chapter 1.7 (Figure 1.7-4). As discussed in Chapter 1.9, most farms within the EIS geographic areas, except for farms in Puerto Rico, are likely to be excluded from the rule.

Data on the characteristics of farming populations include the urban and rural population trends related to movement of the population throughout the United States. Data on these trends were gathered from the USDA Census of Agriculture, the U.S. Census 2010, and the USDA ERS. This section also describes rural employment trends.

While not considered a minority population with respect to this EIS, farms operating within conventional traditional agrarian communities will allow draft or working animals in their fields during growing or harvest times (see Chapter 3.4.3.2). For these communities, specialized farming such as livestock farming and/or growing a high-value crop like tobacco or fresh produce may be necessary to maintain suitable returns to make farming a viable sole livelihood for these small family farms. If the farmer decides that in order to comply with the rule, working animals may no longer be used and they would have to purchase farming equipment, the associated costs may result in significant adverse effects to members of these communities. These effects are not anticipated. Since fencing is not required by the rule, these farms may rely more heavily on a robust monitoring plan in concert with other measures such as to establish and use horse paths that are segregated from covered produce plantings, and to minimize entry of horses in covered produce plantings, thus minimizing the opportunity for horse excreta to contact covered produce. If such actions were taken the economic impact may be considered low.

Environmental Justice

Executive Order 12898, *Federal Actions to address Environmental Justice in Minority Populations and Low-Income Populations*, signed by President Clinton on February 11, 1994, states that "each Federal agency shall make achieving environmental justice part of its mission by identifying and addressing as appropriate, disproportionality high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low income populations." (59 Fed. Reg. 7629, February 16, 1994).

This EIS identifies the potential minority and low-income populations that may be affected by the PS PR, if finalized. For the purposes of this EIS, low-income and minority populations, and FDA's methodology for identifying these populations, are discussed in greater detail in Chapter 3.7.3. Data important for identifying minority and low-income populations potentially affected by the PS PR, if finalized, was also found in the Census of Agriculture (USDA NASS, 2014a). It should be noted that information was not available specific to race as it relates to produce covered by the PS PR; the USDA information does provide data for minority operators by state for general fruits and vegetables.

3.7.2 Regulatory Oversight

Environmental Justice (EJ) guidance under NEPA, as provided by the CEQ (1997a), was established to assist federal agencies in effectively integrating socioeconomic impacts, including those on minority and low-income populations, into their project development procedures. Additionally, the HHS 2012 Environmental Justice Strategy and Implementation Plan provides strategic elements, strategies, and actions to be undertaken by HHS in order to achieve targeted environmental justice goals (HHS, 2012).

3.7.3 Current Background Conditions

Nationwide Overview

The U.S. supported a total of 2,109,303 farms in 2012 which were operated by approximately 3.2 million farmers (USDA NASS, 2014a). This represents a decrease of 95,489 farmers from 2007 data (USDA NASS 2009a). Approximately 99.6 percent of the farms are located in the contiguous 48 states. Table 3.7-1 presents the change in farming from 2002 to 2012 throughout the U.S. by region. The West and Non-Contiguous States have seen the greatest increase in farms since 2002 with an approximate ten and thirty percent increase, respectively. Comparatively, marginal growth has been observed in the Plains region, and a decrease in farms has been reported in the Atlantic, Midwest, and South regions, and in Puerto Rico. Table 3.7-1 identifies the states included within each region. These regions, as defined, are carried forward throughout the socioeconomic analysis.

Table 3.7-1. Regional farm distribution and change (2002-2012)

Region		Agricultural Census Year				
		2012	2007	2002	Total Change (2002-2012)	Percent Change (%)
U.S.		2,109,303	2,204,792	2,128,982	-19,679	-0.92
West	Arizona	20,005	15,637	7,294	12,711	174.27
	California	77,857	81,033	79,631	-1,774	-2.23
	Colorado	36,180	37,054	31,369	4,811	15.34
	Idaho	24,816	25,349	25,017	-201	-0.80
	Montana	28,008	29,524	27,870	138	0.50
	Nevada	4,137	3,131	2,989	1,148	38.41
	New Mexico	24,721	20,930	15,170	9,551	62.96
	Oregon	35,439	38,553	40,033	-4,594	-11.48
	Utah	18,027	16,700	15,282	2,745	17.96
	Washington	37,249	39,284	35,939	1,310	3.65
	Wyoming	11,736	11,069	9,422	2,314	24.56
	Regional Total	318,175	318,264	290,016	28,159	9.71
Plains	Kansas	61,773	65,531	64,414	-2,641	-4.10
	Nebraska	49,969	47,712	49,355	614	1.24
	North Dakota	30,961	31,970	30,619	342	1.12
	Oklahoma	80,245	86,565	83,300	-3,055	-3.67
	South Dakota	31,989	31,169	31,736	253	0.80
	Texas	248,809	247,437	228,926	19,883	8.69
	Regional Total	503,746	510,384	488,350	15,396	3.15
South	Alabama	43,223	48,753	45,128	-1,905	-4.22
	Arkansas	45,071	49,346	47,483	-2,412	-5.08
	Florida	47,740	47,463	44,081	3,659	8.30
	Georgia	42,257	47,846	49,311	-7,054	-14.31

Region		Agricultural Census Year				
		2012	2007	2002	Total Change (2002-2012)	Percent Change (%)
	Louisiana	28,093	30,106	27,413	680	2.48
	Mississippi	38,076	41,959	42,186	-4,110	-9.74
	South Carolina	25,266	25,867	24,541	725	2.95
	Regional Total	269,726	291,340	280,143	-10,417	-3.72
Midwest	Illinois	75,087	76,860	73,027	2,060	2.82
	Indiana	58,695	60,938	60,296	-1,601	-2.66
	Iowa	88,637	92,856	90,655	-2,018	-2.23
	Michigan	52,194	56,014	53,315	-1,121	-2.10
	Minnesota	74,542	80,992	80,839	-6,297	-7.79
	Missouri	99,171	107,825	106,767	-7,596	-7.11
	Ohio	75,462	75,861	77,797	-2,335	-3.00
	Wisconsin	69,754	78,463	77,131	-7,377	-9.56
	Regional Total	593,542	629,809	619,827	-26,285	-4.24
Atlantic	Connecticut	5,977	4,916	4,191	1,786	42.62
	Delaware	2,451	2,546	2,391	60	2.51
	Kentucky	77,064	85,260	86,541	-9,477	-10.95
	Maine	8,173	8,136	7,196	977	13.58
	Maryland	12,256	12,834	12,198	58	0.48
	Massachusetts	7,755	7,691	6,075	1,680	27.65
	New Hampshire	4,391	4,166	3,363	1,028	30.57
	New Jersey	9,071	10,327	9,924	-853	-8.60
	New York	35,537	36,352	37,255	-1,718	-4.61
	North Carolina	30,961	52,913	53,930	-3,712	-6.88
	Pennsylvania	59,309	63,163	58,105	1,204	2.07
	Rhode Island	1,243	1,219	858	385	44.87
	Tennessee	68,050	79,280	87,595	-19,545	-22.31
	Vermont	7,338	6,984	6,571	767	11.67
	Virginia	46,030	47,383	47,606	-1,576	-3.31
	West Virginia	21,489	23,618	20,812	677	3.25
	Regional Total	397,095	446,788	444,611	-28,259	-6.36
Non-Contiguous States	Alaska	762	686	609	153	25.12
	Hawaii	7,000	7,521	5,398	1,602	29.68
	Regional Total	7,762	8,207	6,007	1,755	29.22
U.S Geographic Areas	Puerto Rico	13,159	15,745	17,659	-4,500	-25.5

Source: Census of Agriculture 2012, 2007, and 2002 (USDA NASS, 2014a, USDA NASS, 2009d, and USDA NASS, 2004)

The Census of Agriculture provides information for three levels of operators: principal (or primary) operator, second operator, and third operator. The principal operator is responsible for the primary day-to-day operation of the farm. The operator could be an owner, hired manager, cash tenant, share tenant, and/or a partner. If land is rented or worked on shares, the tenant or renter is the operator. Information is collected for up to three operators per farm. In the case of multiple operators, the respondent for the farm identifies who the principal farm operator is during the data collection process. The number of principal operators is used to determine the amount of farms within the United States. Data presented in Table 3.7-2 is reflective of the number of principal operators on a farm. In 2012, 3.2 million farmers operated 2.1 million farms. There has been an approximate three percent decrease in farms and farm operators since the 2007 Census of Agriculture (USDA NASS, 2014a; USDA NASS, 2009d). Table 3.7-2 presents the decline in farming from 2007 to 2012.

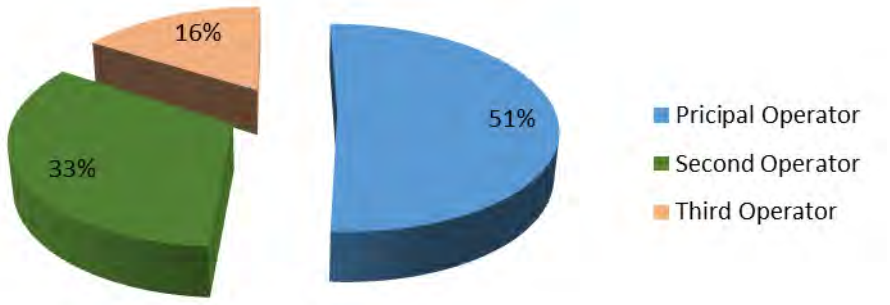
Table 3.7-2. Distribution of farm operators, 2007-2012

Operators	Agricultural Census Year			
	2012	2007	Total Change (2007-2012)	Percent Change (%)
Principal	2,109,303	2,204,792	-95,489	-4.3
Second	928,151	931,670	-3,519	-0.4
Third	142,620	145,072	-2,452	-1.7
Total	3,180,074	3,281,534	-101,460	-3.1

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Figure 3.7-1 presents the U.S. distribution of operator type (USDA NASS, 2014a). These data are the result of the USDA NASS survey data, specifically for 2012, which USDA relies upon to determine the number of farms in the United States.

Figure 3.7-1. Percentage of Operators, 2012



Farm Tenure

The total number of farms has decreased from 2007 to 2012; the amount of land in farms and full ownership (owned and operated by the primary operator) of farms has similarly decreased. Full owners only operated land they owned, while partial owners are defined as persons who operated land they own or rent. The number of farms and total farmland acres by ownership type are described in Table 3.7-3.

Table 3.7-3. Number of farms and total farmland Acres, 2007-2012

	Total	Full Ownership	Partial Ownership	Tenant
Number of Farms 2007	2,204,792	1,522,033	542,192	140,567
Number of Farms 2012	2,109,303	1,428,351	533,070	147,882
Land in Farms 2007 (acres)	922,095,840	343,952,327	496,344,290	81,799,223
Land in Farms 2012 (acres)	914,527,657	336,233,189	491,292,824	87,001,644

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Age of Operators

The trend of increasing operator age, identified in Table 3.7-4, has been observed through previous Censuses of Agriculture. The 2012 Census of Agriculture found the average farm operator age to be 58.3 years, an increase of 8 years from the 1978 Census of Agriculture. The majority of farmers are between the ages of 45 and 64 (51 percent). Farm operators 65 years and older are the second most prevalent (33 percent). There has been a decline in the number of farmers between the ages of 35 to 44 and 45 to 54 according to the 2007 and 2012 Censuses of Agriculture.

Table 3.7-4. Age of operators

Age Range	2012	2007	Percent Change (%)
All Principal Farm Operators			
Under 25 Years	10,714	11,878	-9.8
25 to 34 Years	109,119	106,735	2.2
35 to 44 Years	214,106	268,818	-20.4
45 to 54 Years	466,036	565,401	-17.6
55 to 64 Years	608,052	596,306	1.9
65 to 74 Years	443,571	412,182	7.2
75 Years and Older	257,705	243,472	5.8

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Beginning Farmers[14]

The USDA defines a beginning farmer as an operator with less than 10 years of experience operating a farm as either the sole operator or with others who have operated a farm 10 years or less. The number of beginning farmers has declined significantly since 2007. Table 3.7-5 presents the decline in beginning farmers since 2007. Of the 2.1 million U.S. principal operators in 2012, 25 percent were classified as beginning farmers. Established farmers are defined as those who were on their current operation eleven years or more. Beginning farmers are on average younger than established farmers. The average age of a beginning farmer on their farm for five years or less is 46.9 years old, while the average age of established farmers is 61.4 years (USDA NASS, 2014a). Compared to more experienced farm operators, there is also a higher likelihood of beginning farmers identifying as minorities, working other jobs off the farm, and a lower likelihood that they will state farming as their primary occupation. Farmers on their operations less than five years generally have smaller farms in both acreage and sales. The net gain in sales and acres is smaller for beginning farmers than that of established farmers, and beginning farmers experience higher expense-to-sales ratios. Beginning farmers also received less government payments than established farmers (USDA NASS, 2014a).

Beginning farmers are found across the county, but the top states with principal operators being beginning farmers are Alaska (37%), Rhode Island (33%), Hawaii (33%), Maine (33%), and Florida (31%). The number of beginning farmers growing grain and vegetables has grown since 2007, while there has been a decrease in tobacco and animal farms with beginning farmers as principal operators (USDA NASS, 2014a).

Table 3.7-5. Number of beginning farmers, 2007-2012

Principal Farm Operators	2012	2007	Percent Change (%)
All Beginning Farmers (10 years or less on current operation)	522,058	652,820	-20
5 Years or Less on Current Operation	226,670	291,329	-22
6 to 10 Years on Current Operation	295,388	361,491	-18

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Agricultural Sales

Farm sales within the U.S. have continued to grow, reaching nearly $395 billon in agriculture-related products in 2012. Sales have increased 33 percent from 2007 in each agriculture economic sector. Crop (including fruit and vegetables) and livestock sales accounted for 48 and 19 percent increases, respectively. Crop sales accounted for more than half of all agriculture sales in 2012. Table 3.7-6 presents the 2012 U.S agricultural sales. Thirteen states produced more than $10 billion in agricultural products in 2012 which made up more than 60 percent of the U.S. agricultural sales. These 13 states are presented in Table 3.7-7. California accounted for

[14] These USDA data also include information on ranchers (livestock raising operations) in addition to farmers.

$42.6 billion dollars in sales, and within California, Fresno County had the highest amount with $5 billion in sales of agricultural products (USDA NASS, 2014a).

Table 3.7-6. 2012 U.S. agriculture sales

	2012 ($ billions)	2007 ($ billions)	Percent Change (%)
Crops	212.4	143.7	47.8
Livestock	182.2	153.6	18.7
All Products	394.6	297.2	32.8

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Table 3.7-7. U.S. States in agriculture sales

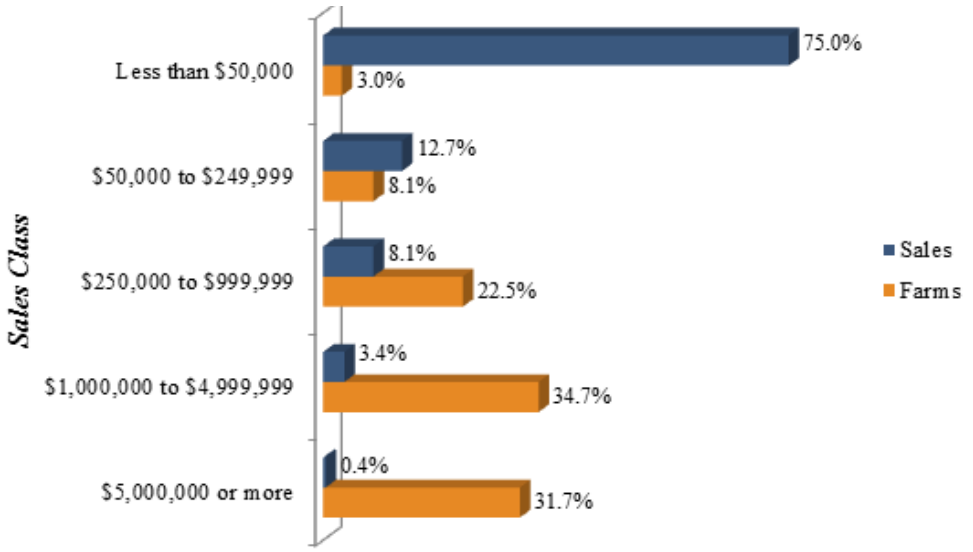
State	2012 ($ billions)	Percent of U.S. Total (%)
California	42.6	10.8
Iowa	30.8	7.8
Texas	25.4	6.4
Nebraska	23.1	5.8
Minnesota	21.3	5.4
Kansas	18.5	4.7
Illinois	17.2	4.4
North Carolina	12.6	3.2
Wisconsin	11.7	3.0
Indiana	11.2	2.8
North Dakota	11.0	2.8
South Dakota	10.2	2.6
Ohio	10.1	2.6

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Farm Size

The majority of farms are small farms, with 75 percent of all farms having sales of less than $50,000. Together, these small farms produce roughly 3 percent of the total value of agricultural products sold. Approximately 95.8 percent of farms have sales of less than $250,000 and account for 33.6 percent of farm sales (USDA NASS, 2014a). Larger farms are not distributed evenly throughout the U.S., with a majority of farms with sales below $50,000 being in located in New England and the Southeast (USDA NASS, 2014a). Figure 3.7-2 shows the distribution of 2012 farm sales by the size of farm. Sales are defined as the gross market value before taxes and production expenses of all agricultural products sold or removed from the place in the year (2012), regardless of who reviewed the payment.

Figure 3.7-2. Share of farms and farm sales, by sales class, 2012



Source: USDA NASS, 2014a

Farm Income

Farm income in addition to agricultural sales includes government payments and earnings from a variety of farm activities. Multiple sources of income are needed to offset farm production expenses. Income through farming is generated from rent, custom work for other farms, forest product sales, recreational services, patronage payments, crop and livestock insurance, and other activities related to agricultural practices. Farm production expenses have continued to increase along with the increase in agricultural sales. The largest expenses related to farm activities are feed, livestock and poultry purchases, fertilizer, labor, and rent for farming property. Government payments have increased nearly 1 percent from 2007, and expenses have increased approximately 36 percent. Government payments to farmers include conservation payments, direct payments, loan deficiency payments, disaster payments, and payments from various government programs (USDA NASS, 2014a). Farm-related income and expenses are described in Table 3.7-8 and Table 3.7-9.

Table 3.7-8. National farm income and expense, 2007-2012

	2012 ($ billions)	2007 ($ billions)	Percent Change (%)
Agricultural Sales	394.6	297.2	32.8
Government Payments	8.1	8.0	0.9
Farm-related Income	18.5	10.5	76.6
Production Expenses	328.9	241.1	36.4
Net Cash Farm Income	92.3	74.6	23.7

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Table 3.7-9. National farm expenses, 2007-2012

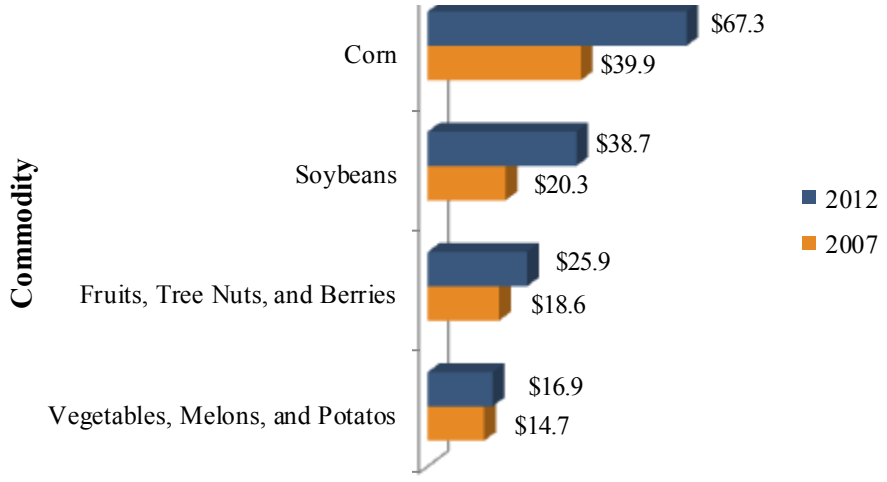
Expenses	2012 ($ billions)	2007 ($ billions)	Percent Change (%)
Feed	75.7	49.1	54.2
Livestock and Poultry Purchases	41.6	38.0	9.4
Fertilizer	28.5	18.1	57.6
Labor	27.0	21.9	23.4
Cash Rent	21.0	13.3	58.2
Seeds	19.5	11.7	66.0
Supplies and Repairs	18.9	15.9	18.7
Gasoline, Fuels, and Oils	16.6	12.9	28.4
Chemicals	16.5	10.1	63.4
Other	63.7	50.1	27.1
Total	328.9	241.1	36.4

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Income from Harvest

The five top grossing commodities in 2012 were cattle, poultry, corn, soybeans and milk. These accounted for 66 percent of the total agricultural sales. Of the crop commodity sales, fruits, tree nuts, berries, vegetables, melons, and potatoes were behind the sales of corn and soybeans, but made increases from 2007 sales. Fruits, tree nuts and berries had sales of nearly $26 billion, and vegetables, melons, and potatoes had sales of approximately $17 billion in 2012 (USDA NASS, 2014a). Figure 3.7-3 presents the 2007 and 2012 sales by commodity sector.

Figure 3.7-3. Top crop commodities by sales, 2007-2012



Source: USDA NASS, 2014a

Value of Harvest

Information related to produce covered by the PS PR is presented below for selected commodities. The farms harvesting the selected crops listed in Table 3.7-10, Table 3.7-11 and Table 3.7-12 make up approximately 15 percent of the total farms listed in the 2012 Agriculture Census.

The vegetable industry is classified by two major end uses: fresh market and processing. Processing is the freezing, canning, and dehydrating of fresh vegetables for consumption. About half of all vegetable production is produced for processing. Most of the vegetable production takes place in California, North Dakota, Idaho, Michigan, Minnesota, Washington and Wisconsin (includes covered and non-covered produce). These areas correspond with regions C, F, E, L, K, M, A, and B which are depicted on Figure 1.7-4 in Chapter 1.7. The Upper Midwest and Pacific States report the largest vegetable acreage for processing (regions: K, L, A, B, and C), while California, Florida, Arizona, Georgia, and New York harvest the largest amount for fresh market consumption (regions: C, U, D, P, T, and R) (USDA ERS, 2014b). More than half of the vegetable production occurs on irrigated land. Vegetable yields continue to grow due to the increase in the use of hybrid varieties and in adoption of precision farming techniques (USDA NASS, 2014a).

During the 2000's fruit and tree nut sales averaged 13 percent of all crop sales, and 6 percent of all farm cash sales. Oranges, grapes, apples and bananas are the most popular fruit; while almonds, walnuts, and pecans are the preferred tree nuts. Output for each has continued to grow due to increased consumption and farming practices. The nation's largest fruit producing states are California, Florida, and Washington (regions: C, U, A and B). California accounts for about half of the harvested fruit acreage (USDA ERS, 2012a). Michigan, New York, Oregon, Pennsylvania, and Texas are other important fruit producing states (regions: L, R, A, B, and R). Fruits are grown for both fresh and processing markets, although more than half of the production is for fresh markets. Processed fruit includes canned, frozen, juice, and dried fruit (USDA ERS, 2012a).

Table 3.7-10. Number of farms harvesting vegetables, 2012

Commodity	2012 Total harvested farms	2012 Farms Harvested for processing	2012 Farms harvested for fresh market
Broccoli	3,636	113	3,580
Cabbage	4,916	228	4,813
Cantaloupe	9,684	31	9,675
Carrots	4,468	304	4,266
Cauliflower	1,330	72	1,295
Celery	488	31	475
Cucumbers	14,183	894	13,571
Curly Endive	109	N/A	109
Garlic	3,408	220	3,306
Herbs (e.g., basil, chives,	2,255	N/A	2,255

Commodity	2012 Total harvested farms	2012 Farms Harvested for processing	2012 Farms harvested for fresh market
cilantro, mint, oregano, parsley)			
Honeydew	534	N/A	534
Lettuce	5,757	N/A	5,757
Onions	8,021	483	7,743
Peas	8,350	2,035	6,546
Peppers (such as bell and hot)	19,519	1,095	18,902
Radish	1,228	34	1,222
Snow Peas	991	86	919
Spinach	1,594	106	1,522
Summer Squash (e.g., patty pan, yellow and zucchini)	14,090	489	13,838
Tomatoes	32,383	2,522	31,047
Watercress	100	N/A	100
Watermelon	12,996	45	12,971

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Table 3.7-11. Number of farms harvesting fruits, nuts, and mushrooms, 2012

Commodity	2012 Total Harvested Farms	2012 Bearing Age Acres Farms	2012 Nonbearing Age Acres Farms
Almonds	7,052	6,285	2,683
Apples	25,129	18,815	12,298
Apricots	2,305	1,654	933
Avocados	7,495	6,919	2,402
Bananas	1,169	970	438
Cherries	10,715	7,660	5,019
Citrus *	13,055	11,886	3,999
Grapes	27,878	23,420	10,092
Guava	399	331	129
Kiwifruit	345	258	131
Mangos	933	800	306
Mushrooms	712	N/A	N/A
Nectarine	1,275	961	509
Papaya	401	339	145
Passion Fruit	153	131	32
Peaches	13,916	9,637	6,895
Pears	10,246	6,631	4,918
Plums	5,888	4,016	2,691
Walnuts	6,656	5,707	2,548

* (e.g., clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and unique fruit)
Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Table 3.7-12. Number of farms harvesting berries, 2012

Commodity	2012 Total Harvested Farms	2012 Farms Harvested	2012 Farm Not Harvested
Blackberries	7,291	5,580	2,542
Blueberries	13,432	10,449	4,951
Raspberries	8,052	6,508	2,303
Red Currant	528	363	218
Strawberries	10,388	8,828	2,764

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Table 3.7-13 provides the 2012 value of harvest for covered produce with information available.

Table 3.7-13. Value of selected covered produce

Crop		Crop Unit	2012 Value of Utilized Production ($1,000) Fresh Market	2012 Value of Utilized Production ($1,000) Commercial Processing
Vegetable Covered Crops	Broccoli	cwt	678,619	8,811
	Cabbage	cwt	388,600	-
	Cantaloupe	cwt	325,337	-
	Carrots	cwt	609,548	33,228
	Cauliflower	cwt	235,620	4,144
	Celery[1]	cwt	366,404	
	Cucumbers	cwt	247,957	172,850
	Curly Endive	cwt	(NA)	-
	Garlic[1]	cwt	227,090	-
	Herbs (e.g., basil, chives, mint, cilantro, oregano, parsley)	cwt	(NA)	-
	Honeydew	cwt	69,826	-
	Lettuce (includes head, leaf, and romaine)	cwt	1,871,511	-
	Onions[1]	cwt	944,029	-
	Peas (includes chickpeas, dry edible peas, and wrinkled seed peas)	cwt	294,195	-
	Peppers (e.g., bell and chili) [1]	cwt	802,685	-
	Radish	--	(NA)	-
	Snow Peas (Austrian Winter Peas)	cwt	3,479	-
	Spinach	cwt	223,622	17,055
	Summer Squash (such as patty pan, yellow and zucchini) [1]	cwt	248,725	-

Crop		Crop Unit	2012 Value of Utilized Production ($1,000) Fresh Market	2012 Value of Utilized Production ($1,000) Commercial Processing
	Tomatoes	tons	863,982	1,010,545
	Watercress	--	(NA)	-
	Watermelon	cwt	520,799	-
Fruits, Nuts and Mushroom Covered Crops	Almonds	Lbs	4,816,860	-
	Apples	Lbs	3,307,635	-
	Apricots	tons	40,879	-
	Avocados	tons	(NA)	-
	Bananas	Lbs	(NA)	-
	Cherries, sweet	tons	843,311	-
	Cherries, tart	Lbs	50,520	-
	Citrus (e.g., clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and unique fruit)	boxes	3,712,817	-
	Grapes	tons	5,657,109	
	Green Beans (snap beans)	cwt	323172	191,635
	Guava	Lbs	(NA)	-
	Kiwifruit	tons	(NA)	-
	Mangos	--	(NA)	-
	Mushrooms	Lbs	109,9400	-
	Nectarine	tons	144,906	-
	Papaya	Lbs	(NA)	-
	Passion Fruit	--	(NA)	-
	Peaches	Ton	629,163	-
	Pears	tons	432,988	-
	Pineapple	--	(NA)	-
	Plums	tons	79,940	-
	Walnuts	tons	1,505,910	-
Berries Covered Crops	Blackberries, cultivated (Oregon)	Lbs	44,520	-
	Blueberries (cultivated & wild)	Lbs	850,883	-
	Raspberries (includes Black, Red, and all California)	Lbs	290,024	-
	Red Currant	--	(NA)	-
	Strawberries	cwt	2,408,596	-

[1] Includes processing and fresh market (USDA NASS, 2014b)

Farm Employment

USDA NASS survey data provides information on principal operators of farms. Limited data is available for farmworkers; however, there is no data specifically reported for farmworkers on produce farms. The U.S. Department of Labor reports some data on farmworkers in terms of ethnicity and income; state-level data are reported for California but no other state. Potential impacts to farmworker employment may be dependent upon multiple factors including (but not limited to) average annual farm income, estimates for crop yield, and commodity prices. Increases in farm operating costs may also impact farmworker employment. It should be noted that farmworker employment can be highly seasonal (USDA ERS, 2014a).

According to the Bureau of Economic Analysis (BEA) data, farm employment is defined as the number of workers engaged in the direct production of agricultural commodities, whether as the sole proprietor, partner or hired laborer. Table 3.7-14 describes the change in farm employment from 2007 to 2012. These data also include various, but not consistent or distinguishable levels of farm operator levels, and not just farmworkers. Therefore, the data presented hereafter may seem somewhat contrary when reporting in terms of numbers of farmworkers. These outcomes depend heavily on the data source, the data collection method, and how and when data are reported. Because these data are collected inconsistently, a comparative analysis is difficult to achieve, and any conclusive analysis cannot be adequately performed.

Table 3.7-14. Farm employment data, 2007-2012

Region	2012	2007	Percent Change (%)
U.S. Total	2,616,000	2,664,000	-1.8
West	572,300	578,022	-1.0
Plains	524,649	534,270	-1.8
South	341,011	353,043	-3.4
Midwest	653,214	669,908	-2.5
Atlantic	511,900	515,497	-0.7
Non-Contiguous States[1]	12,926	13,260	-2.5
Puerto Rico	*	*	*

[1]Includes Alaska and Hawaii
* Data not available
Source: Bureau of Economic Analysis

Hired farmworkers include field crop workers, nursery workers, farm supervisors, and hired farm managers. Hired farmworkers make up less than one percent of the all the U.S. wage and salary workers but are an important part of U.S. agriculture. Farmworkers make up a large part of the costs in labor intensive crops such as fruits, vegetables, and nursery products. Hired farmworkers

are one of the most economically disadvantaged groups in the U.S. (USDA ERS, 2014a), especially farm laborers, as discussed the Farmworkers subsection below.

Farmworkers

The USDA periodically conducts research and takes surveys on farm labor issues. According to the most recent farm labor survey (survey taken in 2012), hired farm employment is estimated at 787,000 nationally (USDA ERS, 2014a). Of these 787,000 workers, 64 percent are reported as having U.S. citizenship, and 42 percent are reported as being foreign born. In addition, an estimated 92 percent of farmworkers are reported as being white (race), and 45 percent are reported as Hispanic (ethnicity). Of the 787,000 farmworkers, 56 percent work in crop agriculture (not broken out by specific crops), and 44 percent work in livestock production. Approximately 37 percent of all hired farmworkers are reported to live primarily Arizona, California, Colorado, New Mexico, and Texas.

The DOL also periodically conducts an employment-based, random survey of U.S. crop workers. The purpose of the survey is to assist the federal government in conducting occupational injury and health surveillance, estimating the number of farmworkers and their dependents, and to conduct planning. [15] Past surveys conducted in 1997 to 1998, and 2001 to 2002 estimated demographic data in terms of "Non-white race" and "Hispanic Ethnicity." These surveys also found that in 1997 to 1998 approximately 61 percent of farmworkers were below the U.S. poverty level and reported a median income for an individual as less than $7,500, and less than $10,000 for a family. For survey years 2001 to 2002 approximately 30 percent of farmworkers were below the poverty level and reported a median income range for an individual as $10,000 to $12,499, and a range of $15,000 to $17,499 for a family (DOL, 2000 and 2005). It should be noted that state-level data is only reported for California (region C).

From these data sets, we can extrapolate that regional data on farmworkers is limited, and yet more data is available for regions C, D, I, and J (including California, Arizona, and Texas).[16]

Environmental Justice

The HHS Mission and Role in Environmental Justice, as identified within HHS's 2012 Environmental Justice Strategy and Implementation Plan, states that "given the persistent, disproportionate burden of environmental hazards on minority and low-income populations and Indian Tribes, HHS will make achieving environmental justice part of its mission by (1) identifying and addressing disproportionately high and adverse human health and environmental effects on minority and low-income populations and Indian Tribes, and (2) encouraging the fair treatment and meaningful involvement of affected parties with the goal of building healthy, resilient communities and reducing the disparities in health and well-being associated with environmental factors."

[15] The DOL Web site specifically reports data limitations including that "except for California, the data are not available at the state level." The Web site is found at: http://www.doleta.gov/agworker/naws.cfm.
[16] Colorado and New Mexico do not have high concentrations of covered produce (see Figure 1.7-4).

Minority Populations:
Pursuant to CEQ's Guidance for Federal Agencies on Key Terms in EO 12898 (CEQ, 1997a), and for the purposes of this Technical Report and the associated EIS, minority populations are comprised of members of the following population groups:

- Black or African American: a person having origins in any of the black racial groups of Africa;
- Hispanic or Latino: a person of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin, regardless of race;
- Asian American: a person having origins in any of the original peoples of the Far East, Southeast Asia or the Indian subcontinent;
- American Indian or Alaskan Native: a person having origins in any of the original people of North America, South America (including Central America), and who maintains cultural identification through tribal affiliation or community recognition; or,
- Native Hawaiian or Other Pacific Islander: a person having origins in any of the original peoples of Hawaii, Guam, Samoa or other Pacific Islands.

Census of Agriculture data were collected on the racial and ethnic composition of vegetable and melon farmers and on fruit and tree nut farmers for each of the regions and the Non-Contiguous States and Puerto Rico (Table 3.7-15). This approach was taken as it presents the most specific breakdown of crops grown by farmer's racial and ethnic composition available based on data provided by the Census of Agriculture. Specifically, the 2012 Census of Agriculture's Table 60, *Selected Farm Characteristics by Race of Principal Operator: 2012,* sheets 1112 and 1113, were used to determine the number of farms with principals operators who identify as minority operators.

Table 3.7-15. Demographics of principal farm operators

Region	Operators Reporting White	Operators Reporting Black or African American	Operators Reporting Asian	Operators Reporting American Indian or Alaska Native	Operators Reporting Native Hawaiian or Other Pacific Islander	Operators Reporting More Than One Race	Total Minority Principal Operators	Percent Minority Principal Operators
U.S.	121,704	2,674	7,033	3,007	461	1,162	14,337	10.5%
West	54,296	200	4,136	2,441	193	424	7,394	12.0%
Plains	8,478	285	79	235	2	105	706	7.7%
South	18,358	1,539	408	141	31	116	2,235	10.9%
Midwest	14,792	114	436	50	14	71	685	4.4%
Atlantic	24,204	524	241	124	10	151	1,050	4.2%
Non-Contiguous States[1]	1,576	12	1,733	16	211	295	2,267	59.0%
Puerto Rico[2]	12,051	1,023	**	**	**	85	1,108	8.4%

[1]Includes Alaska and Hawaii
Source: 2012 Census of Agriculture (USDA NASS, 2014a)
[2]Data includes all farmers.
* Puerto Rico "More than one race reported" also includes individuals who identified themselves as other in the 2012 Census of Agriculture for Puerto Rico.
** Data not available

In accordance with the CEQ guidance, *Environmental Justice Guidance under the National Environmental Policy Act* (1997a), a minority population is found to exist where either (a) the minority population of the affected area exceeds 50 percent of total population or (b) the minority population percentage of the affected area is meaningfully greater than the minority population percentage in the general population or other appropriate unit of geographical analysis. This guidance does not define the specific numerical value or percentage that should be used for determining if the minority or low-income population is "meaningfully greater" than the average in the surrounding jurisdiction. However, it is consistent with the CEQ guidance to set a threshold that is higher than (not equal to) the average of the minority population in the surrounding jurisdiction (in this case, a specific region). For the purposes of this assessment, the population of minority principal operators for each region is deemed to be "meaningfully greater" if it is greater than the value of the country's minority principal operators by 10 percent of that value or more.

The national average of farms with minority principal operators is 10.5%. By applying an additional ten percent of that value (i.e., 1.05%), FDA is able to establish a "meaningfully greater" threshold of 11.6%. Of the regions included within the analysis, we find that both Alaska and Hawaii, and the West region have a minority population of principal operators greater than the 11.6% threshold. Thus, as shown in Table 3.7-15, the Non-Contiguous States

(found to be at 59.0 percent) and the West region (found to be at 12 percent) are considered minority populations for the purposes of this analysis. Table 3.7-16 further breaks down the states within the West region. When compared to covered produce regions (Chapter 1.7, Figure 1.7-4), the regions described in this paragraph include regions A, B, C, D, W, and V.

EIS Geographic Areas

Puerto Rico contains 13,159 principal farm operators as indicated by the 2012 Census of Agriculture. Of the just over 13,000 principal farm operators, 8.4% identify themselves as minorities, which is below the 11.6% meaningfully greater threshold (USDA NASS, 2014c). Census data collected for 2012 is not currently available for other EIS geographic areas. The 2007 Census of Agriculture indicated Guam and the Commonwealth of the Northern Mariana Islands have minority principal farmer operator populations with 97.1% and 97.6%, respectively [2007 Census of Agriculture (Guam and Mariana)]. Information related to race was not provided in the 2007 Census of Agriculture for American Samoa and the United States Virgin Islands [2007 Census of Agriculture (AS and USVI)] (USDA NASS, 2009d). Based on Agricultural Census data it is anticipated that the majority of farms in these other EIS geographic areas would be excluded from the provisions of the PS PR, if finalized, as described in Chapter 1.9.

Table 3.7-16. Demographics of principal farm operators in the West

Region		Operators Reporting White	Operators Reporting Black or African American	Operators Reporting Asian	Operators Reporting American Indian or Alaska Native	Operators Reporting Native Hawaiian or Other Pacific Islander	Operators Reporting More Than One Race	Total Minority Operators	Percent of Minority Principal Operators	Covered Produce Growing Regions Within State
West	Arizona	1,059	10	51	1,373	-	9	1,443	57.7%	D
	California	35,339	156	3,668	526	169	278	4,797	12.0%	A, C, D
	Colorado	996	2	15	6	3	10	36	3.5%	D, E, G, H
	Idaho	1,100	-	23	-	-	3	26	2.3%	B, D, E
	Montana	464	-	6	6	-	2	14	2.9%	D, E, F, G
	Nevada	138	-	10	12	-	1	23	14.3%	D
	New Mexico	3,248	15	17	378	-	34	444	12.0%	D, E, G, H
	Oregon	4,697	4	117	21	5	29	176	3.6%	A, B, E
	Utah	840	1	4	40	4	1	50	5.6%	D, E
	Washington	6,364	12	225	79	12	57	385	5.7%	A, B, E
	Wyoming	51	-	-	-	-	-	-	0.0%	D, E, G
	Regional Total	54,296	200	4,136	2,441	193	424	7,394	12.0%	

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Low-Income Populations:

For the purposes of this EIS low-income persons include any persons whose median household income is at or below the HHS poverty guidelines. While the 2014 HHS poverty guideline data is available, the 2012 dataset is the appropriate data set for a comparison with the 2012 ERS measurement.

Published in the *Federal Register* on January 26, 2012, Table 3.7-17 identifies the 2012 HHS poverty guidelines for the 48 contiguous states and the District of Columbia (77 Fed. Reg. 4034, January 26, 2012):

Table 3.7-17. Poverty guidelines for the 48 Contiguous States and the District of Columbia

Number of Persons in Family/Household	Poverty Guideline[1]
1	$11,170
2	$15,130
3	$19,090
4	$23,050
5	$27,010
6	$30,970
7	$34,930
8	$38,890

Source: U.S. Department of Health and Human Services 2012 Poverty Guidelines (77 Fed. Reg. 4034)

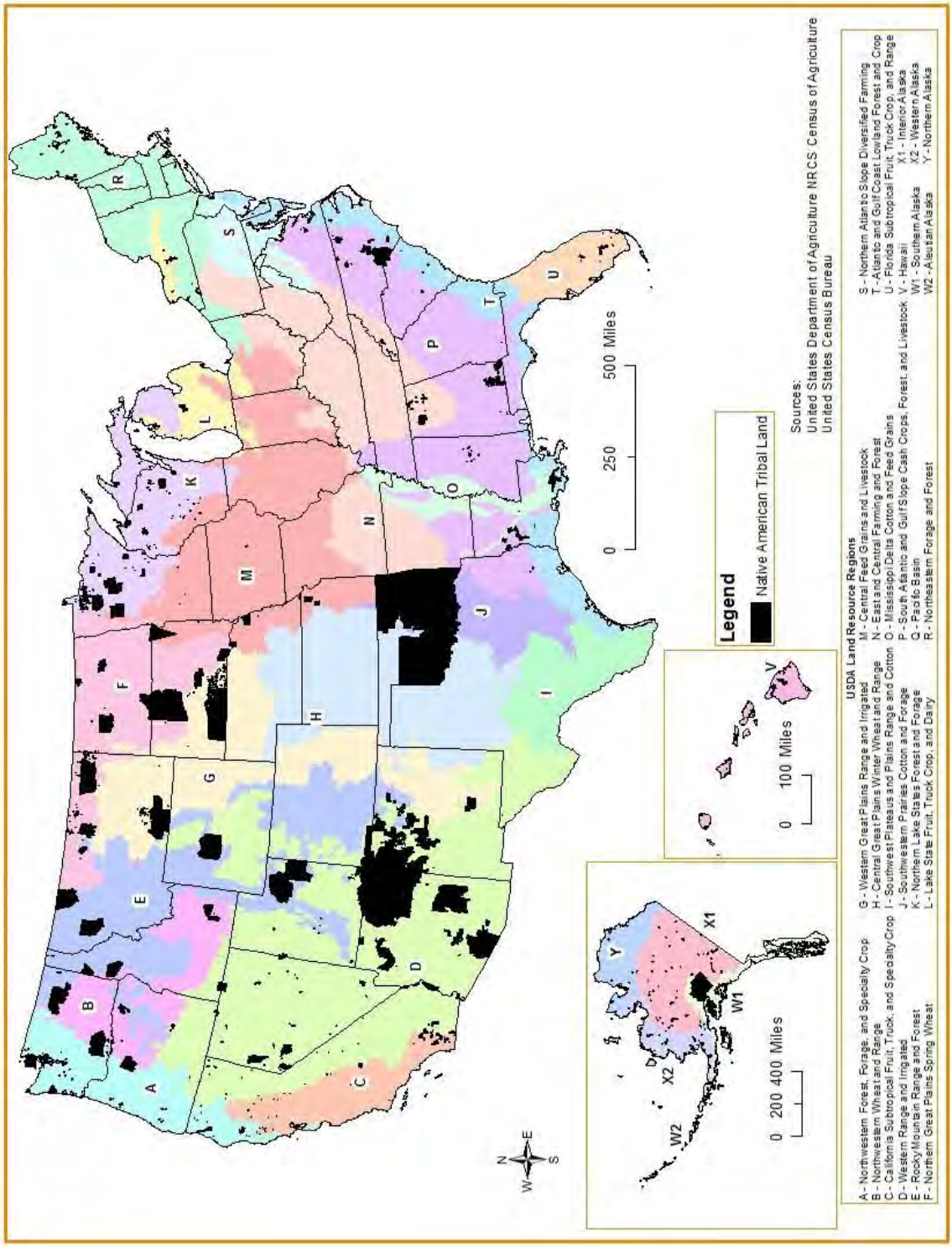
An area is identified as containing a low-income population when the median household income for the area is below the HHS poverty guideline, which was $23,050 for a family of four in 2012 (77 Fed. Reg. 4034). The USDA ERS reports an income measure for farm operator households comparable to the U.S. Census Bureau (USCB)'s measure for all U.S. households. According to the ERS's data sheet, *Principal Farm Operator Household Finances by ERS Farm Typology,* in 2012, median farm operator household income, an average of the farm and off-farm household incomes of residence farms, intermediate farms, and commercial farms, was $68,298 (USDA ERS, 2012b). This exceeds both the median U.S. household income and all of the HHS poverty guideline. Median farm operator household income was not available for the EIS geographic areas.

Tribal Resources:
According to the Bureau of Indian Affairs, a *federally recognized tribe* is "an American Indian or Alaska Native tribal entity that is recognized as having a government-to-government relationship with the United States, with the responsibilities, powers, limitations, and obligations attached to that designation, and is eligible for funding and services from the Bureau of Indian Affairs. Furthermore, federally recognized tribes are recognized as possessing certain inherent rights of self-government (i.e., tribal sovereignty) and are entitled to receive certain federal benefits, services, and protections because of their special relationship with the United States." [17]

There are currently 566 federally recognized tribes located in the United States, with reservations and tribal lands throughout the United States (Figure 3.7-4) each with a wide array of interests and issues which may or may not be relevant or of concern to other tribes. For purposes of the Environmental Justice review, tribal populations are considered part of the total minority population.

[17] http://www.bia.gov/FAQs/index.htm.

Figure 3.7-4. Tribal lands in the U.S.



The U.S. works with Indian tribes to address issues concerning Indian tribal self-government, tribal trust resources, and Indian tribal treaty and other rights. Executive Order 13175 requires U.S. Executive Departments and agencies to actively engage in meaningful collaboration and consultation with tribes' officials in the development of federal policies that have tribal implications.

E.O. Order 13175 and Statutes relevant to tribal resources include:

- Executive Order 13175 and Memorandum (The White House, 2009): Requires executive departments and agencies to engage in regular and meaningful consultation and collaboration with tribal officials in the development of federal policies that have tribal implications.
- The Indian Self-Determination and Education Assistance Act of 1975, as amended (25 U.S.C. § 450 et seq.): Authorized several government agencies (including the HHS) to enter into contracts with Indian tribes and transferred administration controls of the programs under the authorized government agencies to the Indian tribes.
- Tribal Self-Governance Act of 1994 (25 U.S.C. § 458aa et seq.): Permits Indian tribes to contract federal service programs and provides Indian tribes the authority to administer the programs in a manner that will meet the needs of the individual tribal communities.

Tribal Resources

- **Consultation:** The FDA has conducted a number of outreach meetings, webinars, and face-to-face consultations with tribal representatives. The timeline of consultation efforts included in Appendix D illustrate the coordination done to date with tribes regarding the PS PR.

- **Current Baseline Data:** Through tribal coordination and outreach efforts (see Tribal Outreach section in Ch. 1.8 and Appendix D), the FDA was able to distinguish concerns about the PS PR which are specific to potentially affected tribal organizations. Three key issues were initially identified through consultation with tribes: 1) tribal sovereignty rights; 2) tribal water rights; and 3) potential impacts to traditional farming methods.

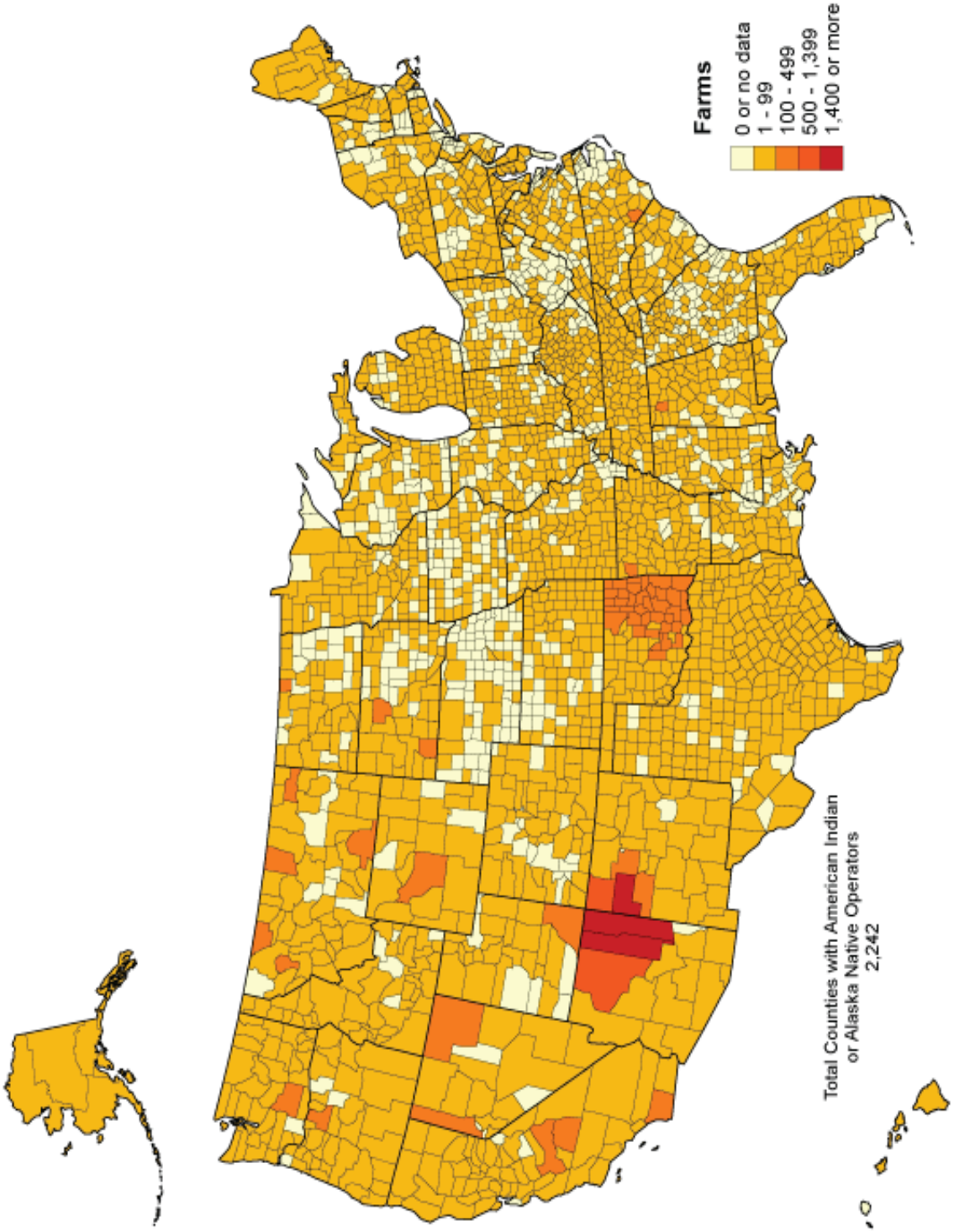
- **Census Data:** Consistent and thorough information on the agricultural operations on tribal lands is lacking. Prior to 1997, each tribal reservation was treated as a single farm, regardless of land ownership and tenancy practices of the individual tribes. Each reservation typically produced a single aggregate report that accounted for all activity on the reservation. In 1997, USDA NASS added a one-page report to the aggregate report, which included the total number of farm or ranch operators on the reservation, a list of counties where the reservation land was located, and the number of operators in each county. The data quality was inconsistent among the field offices—some successfully contacted individual farmers and rangers on reservations, while others gathered only the aggregate information.

In 2002, USDA NASS was encouraged to conduct a more thorough survey of reservation-level data. A pilot project to contact individual farm and ranch operators on tribal reservations was executed in Montana, North Dakota, and South Dakota.

Efforts in the 2007 Census of Agriculture were expanded to include all reservations in all states (USDA NASS, 2009d). The same method was instituted for the 2012 Census of Agriculture. In order to capture a more accurate portrayal of agricultural production on tribal lands, a concerted effort was made to reach every American Indian and Alaska Native farm or ranch operator in the country. However, only a selected number of tribes were identified in the American Indian Reservations reports published for both the 2007 and 2012 Censuses. They were chosen based on approval by tribal officials, the amount of agricultural activity, success of list building activities, and respondent confidentiality.

A general profile of Native American farming practices in the U.S. was published after the 2007 Census of Agriculture was released (an abbreviated demographic profile was published for the 2012 Census). This demographic information, however, profiled the Native American farm operator, rather than farms located on Native American-owned land. Figure 3.7-5 illustrates these findings in 2007.

Figure 3.7-5. Native American Farm owners/operators in the U.S.



While Native American farms are larger in acreage, overall they tend to be smaller in terms of sale of goods (USDA NASS, 2009d). According to information obtained from the 2012 census the following comparisons can be made between Native American farms and all farms (Table 3.7-18):

Table 3.7-18. Comparison of Native American farms with all U.S. farms

Farm Operations	All Farms	American Indian Operated Farms (Both on and off reservation lands)
Average Size of Farms	434 acres	1,021 acres
Average Value of Sales Per Farm	$187,097	$57,081

Source: USDA NASS, 2009d

It is important to note that this is reflective of all farms and all products sold, not just those farms growing covered produce.

According to information obtained from the 2012 Census of Agriculture "...seventy-seven percent of farms with an American Indian principal operator had fewer than 180 acres, and 78 percent had sales of less than $10,000 in 2012" (USDA NASS, 2014a). Table 3.7-19 illustrates the trends in size and sales of farms of those farm operators who are "American Indian Principal Operators" compared to "All Farm Operators":

Table 3.7-19. Farms with American Indian principal operator, by farm size and sales, 2012

Farm Operations		American Indian Operated Farms (percent)	All Farms (percent)
Farm Size	< 50 acres	57	39
	50 to 179 acres	20	30
	180 to 999 acres	15	23
	1,000 acres or more	8	8
	Total	100	100
Farm Sales	< $10,000	78	56
	$10,000 to $49,999	14	19
	$50,000 to $249,999	5	13
	$250,000 to $999,999	2	8
	$1,000,000 or more	1	4
	Total	100	100

Source: USDA NASS, 2014a

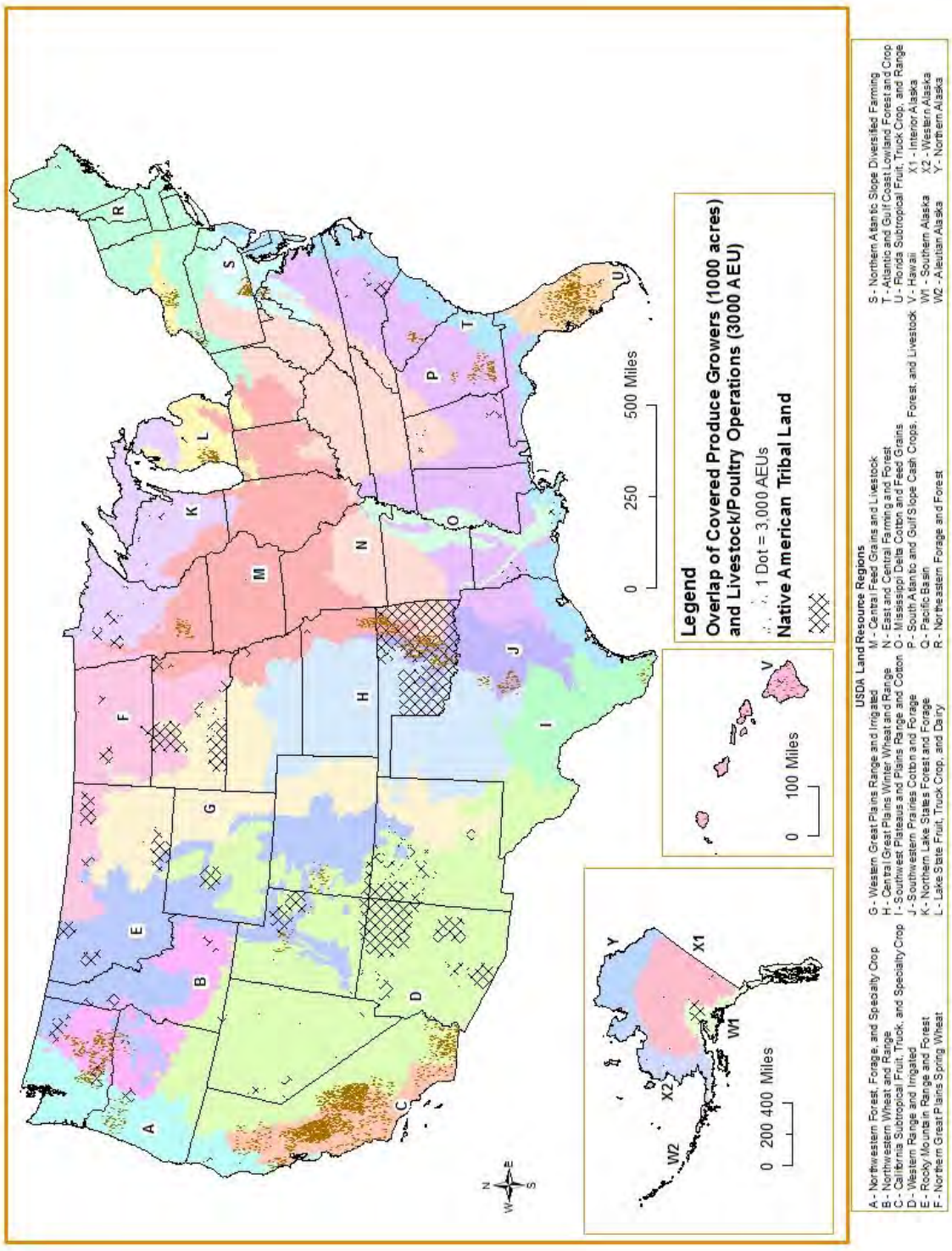
The 2012 Census information also reveals that only 6% of Native American Operated farms grow produce as their principle commodity while another 15% grow some combination of crops as their principle commodity (USDA NASS, 2014a).

Beyond the inconsistencies in data collection from census to census, the breakdown of information provided in the census reports is not detailed enough to show which types of produce are grown by which tribes and thus whether those tribes would be affected by the PS

PR. It is unclear whether the crops produced by tribes and tabulated in the census results are those covered by the PS PR. Although state-specific summaries tabulate "Farms with American Indian or Alaska Native Operators," these summaries track the race/ethnicity of farm operators but do not distinguish whether farms are tribally owned or located on tribal lands. Furthermore, specific census information on individual tribes is not available due to confidentiality laws.

Figure 3.7-6 illustrates tribal lands located throughout the U.S. based on information obtained from the National Atlas of the United States (2014). This information is also useful for analysis although the breakdown of farms on each reservation are not available. To help narrow down regions where tribal lands could be impacted by the PS PR, the map of the tribal reservation lands was overlaid with a map that illustrates areas that have a substantial overlap of livestock and produce production. The resulting map illustrates those areas of the country where tribal lands may have farming operations that are covered by the PS PR. Figure 3.7-6 illustrates these overlaps.

Figure 3.7-6. Native American lands overlaid with areas of covered produce and livestock/poultry operations



Results of this overlay generally indicate two concentrated, though not exclusive, areas in the U.S. where farms on Tribal lands are likely co-located with produce and poultry/livestock operations, these are regions B and J (USDA NASS, 2009d).

To determine whether the PS PR would apply, we attempted to identify the produce operations of Tribes in these regions. The 2007 Census of Agriculture includes information on 73 Native American reservations; however, those tribes profiled in the census results were chosen based on Tribal approval, amount of agricultural activity, success of list building, and confidentiality. Limited information on livestock and produce production is included in the profiles, but only when providing such information would not inadvertently identify individual farmers in the tribe.

Influence of Agriculture that contributes to the background conditions

The following bullets discuss whether potentially significant provisions were raised as a concern to Tribes through the scoping process and through ongoing Tribal consultations.

- **Agricultural Water:** During the EIS scoping period, one commenter raised concern that the rule may result in an increase in groundwater drawdown by agriculture that draws from the same aquifers as Tribes, and that rule potentially may affect Tribes' water sovereign rights. This issue of groundwater drawdown is addressed in Chapters 4.2 and 4.7 of this EIS.

- **Biological Soil Amendments:** There are no data available on the use of BSAs of animal origin by Native American Indian Tribes.

- **Domesticated and Wild Animals (i.e., grazing of domesticated animals and wildlife intrusion):** There are no identified influences from domesticated and wild animals on tribal resources.

- **Businesses Covered by the Rule:** Of all farms that are operated by Native American principal operators, whether located on or off reservations, 5.5 percent report growing vegetables, 2.4 percent report growing fruits and tree nuts, and 15 percent report growing combination crops. There may be farms that produce crops in multiple of these categories, and these categories include both covered and non-covered crops. Therefore, based on a very conservative estimate, no more than 22.9 percent of farms—the sum of these three categories—that are operated by Native American principal operators may be growing covered produce (USDA NASS, 2014a). Based on USDA NASS data (2014a), 78 percent of all Native American farms sell less than $10,000 in total sales, annually, meaning that, at most, 22 percent of farms with a Native American principal operator would be covered farms under the PS PR, if finalized. If it is assumed that these trends are consistent across all commodities, this means that, at most, 5 percent of farms with a Native American principal operator would be covered by the rule (22 percent of 22.9 percent is approximately 5 percent). Moreover, farms that sell less than $25,000 annually in produce—not $10,000—are not covered by the PS PR. An additional 14 percent of

farms with a Native American principal operator sell less than $49,999, meaning there is a reasonable likelihood that additional farms with a Native American principal operator would not be covered by the PS PR, if finalized. It is not possible to estimate what percent of farms lie between $10,000 and $49,999 average annual sales. An additional 5 percent of Native American operated farms have less than $249,999 in total sales.

Summary/Conclusions

Based on comments received from Native American and Alaska Native tribes, tribal concerns are focused mainly on sovereignty issues, including tribal water rights, rather than the environmental impacts of the PS PR.

There is potential for significant environmental impacts to tribal lands based on the water resource impacts identified in Chapter 4 on a regional basis. Geographic regions with moderate to high impacts to water quality were assessed to determine the presence of tribal agricultural lands and a correlation was made between the water quality impacts, the presence of tribal agricultural lands and the potential water usage. The sovereignty concerns are outside the scope of this EIS.

3.8 Human Health and Safety

3.8.1 Definition of the Resource

Evaluating Human Health and Safety in an environmental impact assessment offers a unique opportunity to consider the protection and promotion of human health (WHO, 1987). Components of an environmental assessment for human health and safety concerns typically address three key elements including 1) the analysis of the baseline, 2) the prediction of impact, and 3) the assessment of impact (Fehr, 1999).

The driving force behind the focus on biological resources and alternatives is the direct impact on human health and safety (foodborne illness outbreaks). Part of this increased interest is attributed to more frequent reporting of foodborne illness, the acute symptoms associated with infection, and the ability of outbreaks to reach a large number of consumers (Nithya et al., 2014). The primary emphasis of the PS PR is to minimize the risk of serious adverse health consequences or death from consumption of contaminated produce. Food safety has become a major concern and warranted numerous research studies in the last several decades (Nithya et al., 2014). Part of this increased interest is attributed to more frequent reporting of foodborne illness, the acute symptoms associated with infection, and the ability of outbreaks to reach a large number of consumers (Nithya et al., 2014).

The FDA aims to minimize pathogen exposure, in part, through changes in the practices, processes, and procedures related to manure management, agricultural water use, domesticated animal management, and feral wildlife management, used in the growing, harvesting, packing, and holding of produce for human consumption. This section discusses the current risks to humans from pathogens associated with produce, aspects of overall population health that may be impacted by the PS PR, and current practices or methods available to mitigate any adverse human health and safety impacts.

3.8.2 Regulatory Oversight

Up until the passage of FSMA, food safety regulatory oversight was focused on areas shown to be of highest risk for foodborne pathogen contamination, such as processing, food handling, and manufacturing sectors. Currently, there is guidance available on good agricultural practices, generally such as manuals available through the USDA GAP&GHP program, and commodity-specific guidance, available through marketing agreements such as the California and Arizona Leafy Greens Marketing Agreements.

Relevant current regulations that have human health and safety implications include: FFDCA (first introduced in Chapter 1.1), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1996, CAA (Chapter 3.6), CWA and SDWA (Chapter 3.1), the Occupational Safety and Health Act (OSHA) of 1970, and the Agricultural Worker Protection Standard (WPS). Regulations that are not discussed above as a part of another resource area section are described below. This list is focused on federal regulations and is not meant to be an exhaustive list of all regulations with human health and safety implications.

FFDCA

The FFDCA (21 U.S.C. §301 et seq.), first enacted in 1936, gives the authority to oversee the safety of food, drugs, and cosmetics to the FDA. Relevant to agriculture, the FFDCA provides the authority to set maximum pesticide residue levels on food and animal feed, mandates a primarily health-based standard for setting a maximum residue level, and gives authority to FDA and USDA to monitor and enforce pesticide residues in food (EPA, 2014l).

FIFRA

The FIFRA (7 U.S.C. §136 et seq.) mandates that EPA regulate the use and sale of pesticides to protect human health and preserve the environment. In order to be approved for use, the pesticide must not pose an "unreasonable adverse effect on the environment," which is defined as (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food (EPA, 2014m). Certain pesticides may be applied only by or under the direct supervision of certified pesticide applicators. Certification and training programs are conducted by states, territories, and tribes in accordance with national standards.

The Agricultural Worker Protection Standard (WPS) (40 CFR Part 170) was established to reduce the risk of pesticide poisoning and injury among agricultural workers including those that handle pesticides. 40 CFR 170.1. As such, EPA establishes the Agricultural WPS under the authority of FIFRA (7 U.S.C. 136-136y). The WPS requires that agricultural establishments protect workers from pesticide exposure, train workers about pesticide safety, and provide mitigation measures if exposures were to occur. On February 20, 2014, the EPA proposed changes to WPS to increase protection from pesticide exposure. The proposed changes include: an increase in the frequency and an expansion of mandatory trainings, increased signage for no entry into fields treated with the most hazardous pesticides until residues decline to a safe level, minimum age requirement on pesticide handling, buffer areas surrounding pesticide-treated fields, measures to improve the states' ability to enforce compliance, and making information specific to the pesticide application available to farmworkers (EPA, 2014n).

OSHA

As a result of OSHA (29 U.S.C. §651 et seq.), Congress created the Occupational Safety and Health Administration (OSHA) to ensure safe and healthful working conditions. Farmworkers are exposed to many hazards on the job making agriculture among the most dangerous industries (DOL, 2013). Section 5(a)(1) of OSHA is often referred to as the General Duty Clause. The General Duty Clause (29 USC §654) states that employers should supply employees a workplace free of recognized hazards that are likely to cause death or serious harm and should comply with all OSHA standards, and that employees should also comply with all OSHA standards applicable to their own actions and conduct. Farms are subject to OSHA under 29 CFR Part 1910,

Occupational Safety and Health Standards for Agriculture under 29 CFR Part 1928, and the General Duty Clause.[18]

3.8.3 Current Background Conditions

Data Sources

State and local public health authorities investigate foodborne illness outbreaks and report the information to the CDC, which becomes involved in multi-state outbreaks. The CDC provides summary reporting and data in the Foodborne Outbreak Online Database (FOOD) and FoodNet (as discussed in Chapter 1.4) that are available to the public. There is often uncertainty and complexity in the process to determine vehicles and route(s) of contamination of pathogens on contaminated produce.

Once cases of foodborne illness are reported and classified as an outbreak, the vehicle has to be first determined, then traced back through the supply chain in order to identify potential routes and sources of contamination. Contamination could have occurred at many different points in the supply chain from growing, packing, holding, transporting, as well as at retail or by the consumer. In addition, depending on the pathogen, the symptoms of foodborne illness can onset many hours or even up to a week after consuming the contaminated food, which adds to the difficulty of determining the vehicle in an outbreak.

Due to the fact that foodborne illness may not always be reported and that determining the route of contamination is difficult, there is high uncertainty in determining the number of cases (one person getting sick) or number of outbreaks (many people getting sick at the same time) and there is further uncertainty in determining the vehicle of the case or outbreak. Thus, information available on foodborne outbreaks has certain inherent limitations.

General Conditions

Risk from Pathogenic Microbes

Most microorganisms are made up of a single cell and cannot be seen with the naked eye. Small and inconspicuous, they can be found everywhere, and life on the planet could not exist without them. Bacteria play an important role in maintaining human life by decomposing organic matter, contributing to the carbon and nitrogen cycles, providing protection from diseases, and digesting food. Even though ten trillion cells make up the human body, more than ten times that amount of bacterial cells live on and inside the body (Maczulak, 2011). These mostly beneficial microbes, known as the normal body flora, maintain health and prevent colonization by harmful microbes.

Harmful, disease-causing microbes are called "*pathogens*". Four major microbial pathogens (STEC, *Listeria monocytogenes*, Norovirus, and *Salmonella*), account for the majority of the

[18] https://www.osha.gov/dsg/topics/agriculturaloperations/standards.html.

foodborne illnesses (Newell et al., 2010) for which a precise route is often not determined. While each four major pathogens have been associated with contaminated food, ingestion of contaminated water, contact with infected animals, and contact with an infected person and unsanitary surfaces also serve as exposure pathways (see Chapter 1.7, Table 1.7-1 and Figure 1.7-1).

Listeria monocytogenes, *Salmonella*, STEC, and Norovirus outbreaks on produce have led to numerous deaths in the U.S. in the last several years (Table 3.8-1). All four pathogens have been responsible for foodborne illnesses and hospitalizations (Scallan et al., 2011).

It is estimated that recent outbreaks have been the cause of over 6.5 million cases resulting in foodborne illness and/or hospitalizations, and nearly 800 people have died (Table 3.8-1). Although the incidence of *Salmonella* infection (15.2 per 100,000 population) was lower in 2013 than in 2010–2012, it remains similar to 2006–2008, and well above the national Healthy People objective (11.4 cases per 100,000 population) (CDC, 2014d).

Table 3.8-1. Foodborne illness outbreaks by pathogen, 2000-2008

Pathogen	Mean Number of Annual Cases of Foodborne Illness[a]	Mean Number of Annual Hospitalizations[a]	Number of Deaths[a]
STEC	63,153	2,138	20
Listeria monocytogenes	1,591	1,455	255
Norovirus*	5,461,731	14,663	149
Salmonella	1,027,561	19,336	378

* = produce is a vehicle of transmission of Norovirus, which can be transmitted by farmworkers involved in harvesting, packing, and packaging fresh produce.
a= Numbers are estimations using data from the years 2000 through 2008, and based on the US population in 2006 (299 million persons). Estimates were derived from statistical models with many inputs, each with some measure of uncertainty (Scallan et al., 2011).

In terms of the number of outbreaks and cases associated with fruits and vegetables, 2009-2010 data show that *Salmonella* were responsible for the greatest number of outbreaks (25) and cases (1,183); followed by Norovirus with 24 outbreaks and 755 cases; and combined instances of *E. coli* O157:H7 and *E. coli* O145 (Sapers and Doyle, 2014). 2007-2008 data for *Listeria monocytogenes* indicate 2 outbreaks and 40 cases associated with fruits and vegetables (Sapers and Doyle, 2014). FDA outbreak surveillance data attributed to biological hazards from a longer period (1996-2010) also indicate that *Salmonella* was the number one ranked organism for outbreaks, hospitalizations, and deaths; followed by STEC as the number two ranked organism (FDA, 2013c). Altogether for the period, bacterial pathogens caused 9,106 illnesses (64 percent of cases linked to outbreaks linked to produce; 650 mean annual cases), 1,189 hospitalizations (87 percent of the hospitalizations linked to biological hazards associated with produce; 85 mean

annual hospitalizations), and 24 deaths (89 percent of the deaths linked to biological hazards associated with produce; 1.7 mean annual deaths) (FDA, 2013c).

In FDA's 2013 PRIA (FDA, 2013b), commodities are split into six categories: herbs, leafy greens, melons, sprouts, tomatoes, and other produce (that includes but is not limited to: berries, peppers, peas, onions, and nuts). Approximately 2.7 million illnesses were attributable to covered produce between 2003 and 2008. As presented in the Draft QAR (FDA, 2013c), the USDA's Microbiological Data Program (MDP) is the largest database of microbiological contamination of produce and is statistically representative of commodities sampled. Table 3.8-2 provides results of over 75,000 samples analyzed for enterohemorrhagic *E. coli* (EHEC), STEC, and *Salmonella*. A positive test result indicates that any one of the three pathogens was detected (FDA, 2013c).

Table 3.8-2. Produce with pathogen contamination

PRIA Commodity Category	Commodity	Number of Samples	Number of Positive Samples	% Positive Samples
Herbs	Cilantro	2510	16	0.64%
	Parsley	1706	8	0.47%
Leafy Greens	Spinach	4433	33	0.74%
	Lettuce	13947	34	0.24%
Melons	Cantaloupe	13264	11	0.08%
Sprouts	Alfalfa Sprouts	7055	12	0.17%
Tomatoes	Tomatoes	19017	6	0.03%
Other Produce	Hot Peppers	1995	6	0.30%
	Green Onions	7342	7	0.10%
	Celery	5478	1	0.02%

Sampling data is from the MDP database for the years 2002 through 2009 and includes produce samples analyzed for EHEC, STEC, and Salmonella.

Overall Population Health

In addition to the reduction of pathogenic contamination of covered produce, the PS PR is expected to impact air quality, water quality and the availability and affordability of fresh produce. These indirect impacts will affect overall population health. See Section 3.5 for current state of air quality and Section 3.1 for the current state of water quality and availability.

Worker Health

Farmworker health is protected by several regulations as detailed in Section 3.8.2. In order for farms to comply with the PS PR, farms may increase use of chemical fertilizer and pesticides.

Due to regulations already in place that protect farmworkers, even if farms increase the use of chemical fertilizer and pesticides, risks to farmworkers are not expected to increase as long as farms stay in compliance with regulations established for the protection of worker health.

Human Health and Safety and the PS PR

Each of the provisions of the PS PR is intended to have a beneficial impact on human health and safety by reducing pathogenic contamination of covered produce. According to the 2013 PRIA (FDA, 2013b), the PS PR is expected to prevent an estimated 1.57 million illnesses. See Table 3.8-3 below for likelihood of contamination and expected reduction in illnesses by contamination pathway. As discussed above, the provisions may have unintended impacts to other aspects of overall population health. Potential impacts to overall population health are discussed by provision type below. Estimated illnesses prevented based on farm size (average annual sales), as presented in the 2013 PRIA, is provided in Table 3.8-4.

Table 3.8-3. Reduction in contamination and prevented illnesses by relevant contamination pathways

Contamination Pathway	Likelihood of Contamination*	Efficacy of Proposed Controls	Mean % Reduction in the Risk of Contamination*	Illnesses Attributed to Produce (millions)	Illnesses Prevented (millions)
Agricultural Water – growing and harvest	16%	54%	8.9%	2.7	0.24
Agricultural Water – post harvest	14%	73%	10%		0.28
Biological Soil Amendments	14%	66%	9.1%		0.24
Domesticated and Wild Animals	14%	58 %	8.2%		0.22

Data from the 2013 PRIA (FDA, 2013b)

*Worker health and hygiene and equipment, tools, building and sanitation contamination pathways were not considered here but with the consideration of growing and harvest and post-harvest activities, these pathways account for approximately 30% (worker health and hygiene) and 10% (equipment, tools, building, and sanitation) of contamination. With the consideration of proposed controls on all contamination pathways, illnesses attributable to produce are expected to decrease by approximately 65%.

Table 3.8-4. Results of different small size-based farm exclusions

Farm Income (Annual average food sales)	Prevented Illnesses (millions)	Illnesses Not Prevented	Covered Farms Covered Farms	Exempt Farms	Produce Acres not covered
<$25K	1.73	-	40,211	149,426	14%
<$50K	1.69	47,000	28,253	161,384	16%
<$100K	1.63	52,000	20,140	169,497	19%

Data is from the 2013 PRIA (FDA, 2013b). In the supplemental proposed rule (79 FR 58434), farm exclusions were modified to include exclusions based on produce sales instead of food sales. Recalculations of all the above scenarios have not been released but estimates, and especially differences between scenarios, are not expected should not change significantly. For example, the percent of produce acres not covered from a $25K value of produce rather than foods is 15 rather than 14 percent.

Recommended Practices Available

Pathogen Reduction Methods

The duration of a foodborne illness outbreak is partially dependent upon the effect of environmental factors on the source of contamination. While high temperatures, sunlight exposure, and unfavorable environmental parameters can be detrimental to foodborne pathogens, many can still persist under a wide range of conditions. For example, *Listeria monocytogenes* can grow and survive outside the host and tolerate a wide range of environmental conditions (higher and lower pH than typically found in the environment, zero to high salinity, and refrigeration temperatures), allowing the pathogen to survive in food processing facilities and a number of food products (Ferreira et al., 2014). Numerous food safety measures have been established to minimize contamination of produce (see next section), however outbreaks continue to occur.

While some of these risks can be minimized, for example through composting or drying manure (Pell, 1997), there has been an increased interest to characterize the mechanisms of microbiological hazards associated with produce outbreaks to help minimize occurrences of illness (Ferreira et al., 2014; Wijands et al., 2014). Research examining where pathogens are most likely to attach to produce have been variable (Kroupitski et al., 2011), although studies demonstrating pathogen survival on different age group of produce have shown persistence of pathogens throughout the growing season (Moyne et al., 2011).

With the pathogen's ability to persist under various conditions, researchers have been developing models to determine the impact of varying modes of handling, packing, and transporting fresh produce on pathogen levels (McKellar and Delaquis, 2011; Pérez Rodríguez et al., 2010; Posada-Izquierdo et al., 2013; Zeng et al., 2014). Many of these models consider hazard controls (i.e., chlorine washing), retail storage and display, and die-off tied to temperature fluctuations.

Generally due to low cost, chlorine is the most widely used agent for post-harvest treatment of fresh produce (Sapers, 2014). However, chlorine is inactivated when in it comes into contact with organic material and can form unsafe compounds (Al-Nabulsi et al., 2014). Due to potential risk of mutagenicity and carcinogenicity of chlorine and maintenance costs due to corrosivity, additional washing agents and new ways to treat fresh produce have been developed (Sapers, 2014).

Chlorination, UV radiation, heat treatments, and hydrochloric acid (HCl) have long been recommended methods to reduce pathogen presence on seed (Lewis Ivey et al., 2014). However, research has continued to explore other means of controlling microbiological hazards at various stages of growing, harvesting, and post-harvest that can be effective without damaging the product. For example, see food-grade detergents (Keskinene and Annous, 2011), natural antimicrobials (Techathuvanan et al., 2014), rice vinegar (Chang and Fang, 2007), use of epiphytic bacteria (Lopez-Velasco et al., 2010), bacteriophages (Hagens and Loessner, 2010), irradiation (Niemira and Zhang, 2014), pulsed light (Niemira and Zhang, 2014), and sonication (Niemira and Zhang, 2014). New ways to treat irrigation water that are reported include: dielectrophoretic phenomena (Wu and Wu, 2008), mannosylated nanoparticles (Qu et al., 2005), and cold plasma (Critzer et al., 2007; Niemira and Zhang, 2014). Most produce is not expected to have pathogens transmitted by seed, but for sprouts and possibly tomatoes, it is reported that seed sanitizers (Lewis Ivey et al., 2014) may reduce pathogen contamination. The use of antimicrobial chemical substances or other methods used to reduce the presence of microbes in or on produce would likely be subject to both EPA and FDA regulation.

Farm Practices

As stated above, agricultural water, biological soil amendments, domesticated and wild animals, and seeds have the potential to introduce pathogenic microbes and contaminate produce. Currently, there is agency and industry guidance available (see Chapter 2.1) on best practices that help to reduce the risk of pathogen contamination. There are also several commodity-specific marketing agreements that farms in several states may choose to enter (or may be mandatory in some cases, such as for tomatoes grown in Florida). When the guidance is followed and farms opt into voluntary audit programs, the risk of pathogen contamination may be reduced.

Methods to Analyze Impacts

The purpose of the PS PR is to minimize the risk of serious or adverse health consequences and death from consumption of contaminated produce, thereby improving human health and safety. Direct impacts to human health and safety focused on reduction of pathogenic outbreaks determined by the amount of covered produce the PS PR may affect. Although reduction in produce-related outbreaks is a focus of the PS PR, overall population health is also important. The PS PR may have unintended, direct and indirect impacts to human health and safety that are unrelated to pathogen reduction, such as potential negative impacts on air or water quality. Thus, these indirect impacts were also considered in Chapter 4.

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4.0 Environmental Impacts

This chapter presents the potential environmental impacts, including human health impacts and related socioeconomic impacts, likely to result from the implementation of FDA's proposed action to establish standards for growing, harvesting, packing, and holding produce for human consumption. Specifically, this chapter analyzes certain FDA proposed requirements (as specified in the 2013 proposed rule and the supplemental proposed rule, taken together) which FDA determined, if finalized, may significantly affect the quality of the human environment. In addition, this chapter analyzes a range of alternatives to these requirements (as presented in Chapter 2.1), as well as the combined environmental impacts of the proposed rule as a whole, if finalized. To help put potential environmental impacts into context, FDA, in coordination with USDA, identified potential management decisions or actions that businesses affected by any final rule might take in order to come into compliance with, or to potentially avoid being subject to, the requirements, if finalized (e.g., by changing to non-covered produce commodities or other crops that are not produce and, therefore, would not be subject to the final rule). No new management decisions or alternatives are evaluated in this chapter as a result of public comment on the Draft EIS. This chapter also evaluates the environmental impacts from FDA deciding to not implement the PS PR: this is the No Action Alternative. At the end of this chapter, FDA identifies the preferred alternative (Chapter 4.8) as well as mitigations (Chapter 4.9) that are intended to assist farmers affected by the rule, if finalized, with understanding and implementing compliance requirements associated with the rule (e.g., training, outreach, education).

Organization of Environmental Consequences

This chapter is divided by the potentially significant provisions (as first discussed in Chapter 1.2) that FDA identified through the scoping process, preparation of a Draft EIS, and preparation of a Final EIS—including the process of reviewing and responding to comments submitted to the Draft EIS—that may significantly affect the quality of the human environment, if finalized; these include:

- (Subpart E) Standards Directed to Agricultural Water
- (Subpart F) Standards Directed to Biological Soil Amendments of Animal Origin
    - Subdivided by treated and untreated amendments
- (Subpart I) Standards Directed to Domesticated and Wild Animals
    - Subdivided by domesticated animal grazing and animal intrusion
- All Proposed Standards including (Subpart A) General Provisions (Cumulative Impacts)

Each Subpart in Table 4-1 further contains alternatives that FDA considered for each potentially significant provision; these include:

Table 4-1. Potentially significant provisions and alternatives analyzed for the PS PR

Potentially significant provisions and alternatives		
Subpart E Microbial Standard for Agricultural Water	**Alternative I.**	Generic *E.coli*: GM of 126 CFU/100 ml and STV of 410 CFU/100 ml, with additional flexibility for microbial die-off and/or removal (Proposed § 112.44(c))
	Alternative II.	Generic *E.coli*: maximum of 235 CFU/100 ml for any single sample or a rolling GM of no more than 126 CFU per 100 ml
	Alternative III.	As proposed (i.e., Alternative I), along with an additional criterion establishing a maximum generic *E. coli* threshold
	Alternative IV. (IV-a, IV-b, IV-c)[1]	Above three alternatives (considered separately), including drip-irrigated root crops
Subpart F Biological Soil Amendments of Animal Origin	**Untreated: Alt. I.**	9-month application interval of untreated BSAs of animal origin in a manner where there is a reasonable possibility that it will contact covered produce after the application (Originally proposed as § 112.56(a)(1)(i)-Decision Deferred)
	Untreated: Alt. II.	Zero days application interval
	Untreated: Alt. III.	Application interval consistent with organic regulations
	Untreated: Alt. IV.	6-month application interval
	Untreated: Alt. V.	12-month application interval
	Treated: Alt. I.	Zero days application interval (Proposed § 112.56(a)(4)(i))
	Treated: Alt II.	45-day application interval
	Treated: Alt. III	90-day application interval
Subpart I Domesticated and Wild Animals	**Grazing: Alt. I.**	Adequate waiting period between grazing and harvest (Proposed § 112.82)
	Grazing: Alt. II.	Minimum waiting period of 9 months
	Grazing: Alt. III.	Minimum waiting period of 90/120 days
	Animal Intrusion: Alt I.	Monitoring evidence for animal intrusion immediately prior to harvest and as needed during the growing season (Proposed, §§ 112.83 and supplemental proposed 112.84)
	Animal Intrusion: Alt II.	Measures to exclude wildlife
Subpart A General Provisions	**Alternative I.**	$25,000 threshold (all produce) (Proposed §112.4)
	Alternative II.	$50,000 threshold (all food)
	Alternative III.	$100,000 threshold (all food)
	Alternative IV.	$25,000 threshold (covered produce only)

The baseline conditions required to analyze the potential environmental impacts, as well as many of the management decisions that could be chosen for each provision and its corresponding

[1] Chapter 2.1 subpart E discusses the three subalternatives that are included under Alternative IV; Alternative IV-a applies the standard as proposed under Alternative I (proposed § 112.44(c)) and also applies the standard to root crops that are drip irrigated or use other low-flow irrigation measures. Similarly, Alternatives IV-b and IV-c apply the standard proposed under Alternatives II and III respectively, and also applies those standards to root crops.

alternatives, tend to overlap significantly. Therefore, relevant background information on baseline conditions is summarized at the start of the analysis for each of the provisions. These summaries are followed by discussions of the potential issues related to the management decisions identified by FDA for the alternatives and the range of potential environmental impacts that are likely. Resource components where no significant effects have been identified are noted and excluded from further analysis in this chapter. Finally, the environmental impacts for each alternative are evaluated with comparison to the baseline and/or other alternatives, as appropriate. In many instances the impact rating, defined below, is the same across several alternatives.

Impact Definitions and Thresholds

FDA is required to consider the potential significance of impacts in terms of both context and intensity (40 CFR § 1508.27).

FDA conducted the analysis on a broad, programmatic level approach consistent with the 2014 CEQ guidance "Effective Use of Programmatic NEPA Reviews" (CEQ, 2014a). As established in Chapter 1.9, FDA determined that the appropriate geographic scale of this EIS is the national and regional level. We also considered the state level where information or data was available. In addition to Chapter 1.9, Chapter 2.1 provides the reader with context for existing industry practices, agency guidance, or regulatory conditions that growers of covered farms may already rely on to incorporate some level of food safety into their business. Furthermore, Chapter 3 helps the reader establish the context of the proposed action by presenting the major regions where covered produce is grown, along with information on the background environmental conditions for each resource component. As required by 40 CFR 1508.27(a), we considered both short- and long-term effects.

The requirement to evaluate based on intensity "refers to the severity of the impact" (40 CFR 1508.27(b)). When considering intensity of certain impacts, FDA took into consideration information obtained in consultation with the USDA and the USFWS.

In evaluating intensity, FDA considered the factors that should be considered under 40 CFR 1508.27(b), including impacts that may be both beneficial and adverse; the degree to which an impact affects public health or safety; the degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks; the degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration; and whether the action is related to other actions with individually insignificant but cumulatively significant impacts.

The current conditions that may contribute to the severity of impacts to specific resource components are summarized in Chapter 4.1. The management decisions a farmer may make that can further contribute to the severity of impacts are assessed in Chapters 4.2 through 4.7.

For all resource components, FDA considers factors such as the number of farms that may be affected by provisions of the rule and whether, based on the broad geographic distribution of all covered farms, the potential environmental impacts on a regional or national basis would be

significant. Where possible, FDA used quantifiable relationships to aid with the establishment of significance factors, such as the number (and corresponding percentages) of covered farms that may be affected by certain provisions of the rule; for example, Chapter 2.1 identifies the estimated number of covered farms that apply untreated BSAs of animal origins, which subsequently is used with other information we obtained regarding BSAs of animal origin to estimate significance in Chapter 4.3. Where an action may result in impacts that are not quantifiable, e.g., the generation of criteria air quality pollutants, FDA assesses impacts using a qualitative approach.

Based upon our use of context and intensity, we are able to apply the terms "significant" and "not significant" impacts to resource components and management decisions evaluated in this EIS. The meaning of each term, for purposes of this EIS, is as follows:

Not Significant: In some cases an impact may be adverse but not significant within the meaning of NEPA. There would be minimal, moderate or no measureable changes to the environment or resource component investigated.

> Minimal - The impact is detectable, and likely reversible, resulting in minor beneficial or adverse impacts.
>
> Moderate - The impact is detectible to a greater extent than minimal, but impacts are not persistent or irreversible on the resource area.

Significant: The impacts to the environment or resource component are readily apparent (i.e., severe) on their own, or in the context of existing environmental conditions any additional impacts could result in a substantial change to environmental conditions.

FDA notes that what constitutes a significant impact will vary by resource component depending on existing conditions.

Accordingly, the following subsection, "Considerations influencing significance," provides the reader with an explanation about how we apply the terms "significant" and "not significant" in this EIS for each resource area. Our use of these terms is consistent with the meaning of context and intensity in § 1508.27 (as summarized in Table 4-2). Our use of the term "impacts" includes only those environmental impacts that are effects (direct and indirect) that would be caused by our PS PR, if finalized (see 40 CFR 1508.8). As stated in Chapter 1.9 and in Appendix E, we are considering impacts at a national, regional, and where possible, state level. The impacts described below do not refer to local impacts. The impacts considered are consistent with the scope of the EIS, as discussed in Chapter 1.9.

Considerations influencing significance

Water Resources

Significant

We evaluated significance for impacts to water resources as those that would impact water availability or water quality, either individually or cumulatively. For water availability, we evaluated whether there would be an increase in surface water use that reduced availability or that caused a shift to, or an increase in, the use of groundwater in geographic areas that are affected by drought conditions, or other adverse impacts on groundwater supplies such as saltwater intrusion. We consider any additional groundwater depletion in regions where current conditions for groundwater depletion are already causing significant impacts to be a significant environmental impact. We consider any increase in surface water use that reduces availability for human or animal consumption or other activities to be a significant environmental impact.

We consider an impact on water quality to be a significant environmental impact if it is expected to result in concentrations of agricultural chemicals, particulates or other materials at a level sufficient to cause adverse public health impacts, or reduce sustainability of vegetation, habitat, or wildlife, generally, either through contamination of, or reduction in habitat quality.

Not significant

If there is no change in water use or availability or no impacts on the sustainability of vegetation or habitat, and wildlife health and survival, and therefore no change to the status quo, there is no environmental impact to water resources for us to consider. If there is a change in water use from surface or ground water, but the water supply can recover to ambient conditions and through normal seasonal and/or annual cycles, the impact is not considered to be significant. This outcome would be considered reversible. If there is a reduction in water quality that results in impacts on individual organisms but populations are readily able to recover, impacts are considered reversible and not persistent, and therefore, not significant.

Biological and Ecological Resources

Significant

For the purposes of this document, we define Biological and Ecological Resources to include wetlands, plants, and animals. We evaluated significance for impacts to wetlands as those that would impact the quality or the function of wetland systems. A systematic loss or reduction in wetland quantity or function detectable on a national or regional level would be a significant environmental impact.

We evaluated impacts to plants as impacts associated with the removal or destruction of critical habitats. The wholesale clearing of plant species on a national or regional level would be considered to be a significant impact to this resource.

Similarly, the destruction of a wildlife species or critical habitat that supports a specific wildlife species, would rise to the level of significant if the effects cause an overall decrease in the amount or health of the resource on a national or regional level.

Not significant

An impact would be considered not significant if enacting the provisions of the PS PR would have an overall minor adverse or beneficial impact on wetland resources. Impacts associated with implementation of the PS PR on wetland resources would be considered to be minimal and not significant if the impact is detectable, but likely reversible through the federal/state wetland permitting and mitigation processes. Moderate impacts to wetlands, which would be detectable to a greater extent than minimal impacts, would be considered not significant if they are not persistent or irreversible.

If there are no detectable changes on a national or regional level to plants and animals, there are no environmental impacts to plant and animal resources for us to consider. If changes are detectable but reversible through changes in wildlife management policies and are not persistent, the impact is not significant.

We also consider there to be no significant impacts if the actions of farmers would not result in unreasonable impacts to vegetation and wildlife at a national or regional level such that these resources could not recover to sustainable populations.

Soils

Significant

We evaluated significance for impacts to soils as those that would result in a permanent change in the natural processing of soil functions such that due to soil compaction, the result is a reduced ability to partition water for groundwater recharge (thus the natural hydrology is permanently altered). These significant impacts may result from a deliberate and essential shift from surface water to groundwater across a broad geographic region, thereby further depleting an aquifer and causing irreversible impacts related to soil compaction. Such irreversible impacts on soils may result in corresponding significant impacts on the ability of those soils to filter nutrients, chemicals and pathogens.

Not significant

If there is no change to the use of the soil such that soil properties remain relatively constant, and therefore no change to the status quo, we consider there to be no environmental impact to soils. If there are changes to soils (e.g., change in livestock grazing location that could result in soil surface compaction) to the extent that such changes are reversible (e.g., by allowing land to go fallow or by rotating the field in use), these impacts are not considered significant. Similarly, farms switching from BSAs of animal origin to another fertilizer source would not be considered

significant if soil functions are not considerably altered and impacts may be reversible such as through the use of no-till techniques or switching to green manuring.

Waste Generation, Disposal, and Resource Use

Significant

We evaluated significance for impacts as those that would result in the abandonment of manure or composted manure as a soil amendment for covered produce production, or the need to store and manage excess manure during the composting process if these activities are not done properly. Excess manure, if not stored in a manner so as to minimize run-off to water bodies, could result in impacts such as nutrient overload, thereby impacting water quality, habitat, and wildlife. If a high number of farms attempting to comply with the rule make a decision to abandon manure or switch to composting manure and store and manage the manure in a way that it is readily available for run-off to receiving water bodies over a broad geographic region or nationwide, we would consider this to be significant.

Not significant

Slight shifts in management practices, or those shifts that are essential to more effectively manage untreated or composted material, but that result in no difficulties in properly storing, using, or disposing of excess animal waste or treated material, are considered not significant.

Air Quality and Greenhouse Gases

Significant

We considered as significant impacts those associated with the production of various components of air emissions considered to be pollutants. These included particulate matter (PM), carbon monoxide (CO), sulfur dioxide (SO2), ozone (O3), lead (Pb), and nitrogen dioxide (NO2) emissions, or increases in other GHG emissions. An impact was considered to be significant if the emissions may result in considerable short- or long-term public health concerns.

Not Significant

If there is no change in ambient air quality (i.e., no change in the status quo), then there is no environmental impact to air quality. An impact will be considered to be not significant if enacting the provisions of the PS PR would not contribute to considerable public health concerns.

Socioeconomics and Environmental Justice

Significant

We evaluated significance for impacts as those that would result in substantial changes in the availability of employment, including those which may result in disproportionate impacts to

minorities, on a national and regional level, due to management decisions to no longer grow one or more produce commodities. We also considered the ability of minority populations to own and operate covered farms as a result of implementing the PS PR. If employment opportunities were reduced on a national or regional level, or minority populations experienced difficulty owning and operating covered farms, we would consider these impacts to be significant.

In addition, an impact would be considered to be significant if it was reasonably foreseeable that changes in water application methods would reduce a Tribe's access to water.

Not Significant

An impact is considered to be not significant if there are no disproportionate impacts on the availability of employment or the opportunity to own and operate covered farms by minority populations. An impact is also not significant if there are minimal or no changes to land management practices on a national or regional level.

Human Health and Safety

Significant

We evaluated significance for impacts as those that would result in either adverse or beneficial impacts to Human Health and Safety. Impacts would be considered significantly adverse if human exposure, including exposure to agricultural workers, to chemicals used in an effort to comply with the PS PR resulted in adverse health effects on a national or regional level. Impacts would also be considered significantly adverse if the PS PR increased the risk of serious adverse consequences or death from foodborne illness outbreaks resulting from pathogens.

Significantly beneficial impacts would be associated with the PS PR by minimizing the risk of serious adverse health consequences or death from covered produce.

Not Significant

An impact was considered to be not significant if chemical exposures to workers or the general public was not likely to result in unreasonable adverse public health impacts.

Table 4-2. Impact threshold values by resource component

Resource Analyzed and Impact Threshold(s)		
Water Resources	Significant	• An impact will be considered significant if there would be shifts in sources of irrigation water from surface to groundwater or from an increase in surface or groundwater use at rates that are sufficient to: o Result in seasonal impacts, where water resources may not adequately recover to ambient conditions on an annual cycle due to natural flushing of the groundwater and increased stream flows during periods of higher precipitation and snow melt; o Initiate or add to the long-term depletion of the aquifer; o Reduce streamflow to levels endangering ecological resources; and/or, o Cause land subsidence and potential irreversible impacts to soils. • Impacts may be persistent or irreversible either on a short- or long-term basis if the impacts compromise water quality.
	Not Significant	• An impact will be considered not significant if enacting the provisions of the proposed rule would not have an adverse or beneficial impact on water resources, or if any adverse impacts associated with the proposed rule, if finalized, could be reversible, such as through the ability to recover the resource from temporary adverse impacts (e.g., allowing water resources to adequately recover to ambient conditions and normal seasonal and/or annual cycles).
Biological and Ecological Resources	Significant	• A systematic loss or reduction in wetland quantity or function on a national or regional level would be a significant environmental impact. • The wholesale clearing of plant species on a national or regional level would be a significant impact to this resource. • Similarly, the destruction of a wildlife species or critical habitat that supports a specific wildlife species would be a significant impact if the effects cause an overall decrease in the amount or health of the resource on a national or regional level.
	Not Significant	• Impacts associated with implementation of the PS PR on wetland resources would be considered to be minimal and not significant if the impact is detectable, but likely reversible through the federal/state wetland permitting and mitigation processes. • Moderate impacts to wetlands, which would be detectable to a greater extent than minimal impacts, would be considered not significant if they are not persistent or irreversible. • If wildlife changes are detectable but reversible through changes in wildlife management policies and are not persistent, the impact is not significant. • We also consider there to be no significant impacts if the actions of farmers would not result in unreasonable impacts to vegetation and wildlife at a national or regional level such that these resources could not recover to sustainable populations.
Soils	Significant	• An impact will be considered significant if the effect on soil resources would change the natural processing of soil functions, and the change would be irreversible.
	Not Significant	• An impact will be considered not significant if the effect on soil resources would have no irreversible change in the processing of soil functions.

Resource Analyzed and Impact Threshold(s)		
Waste Generation, Disposal, and Resource Use	Significant	• An impact will be considered significant if abandonment of manure or composted manure as a soil amendment would cause widespread storage and handling problems to the animal raising industry, such as livestock and poultry farmers being forced to dispose of excess manure by sending it to a landfill or over-application to their own land (non-covered produce crops and pasture) to the degree it would cause nutrient laden runoff or leachate.
	Not Significant	• An impact will be considered not significant if the animal raising industry encounters minimal or no difficulties in storing, using, or disposing of excess animal waste.
Air Quality and Greenhouse Gases	Significant	• An impact will be considered significant if particulate matter (PM), carbon monoxide (CO), sulfur dioxide (SO2), ozone (O3), lead (Pb) or nitrogen dioxide (NO2) emissions or increases in other GHG emissions result in considerable short- or long-term public health concerns.
	Not Significant	• An impact will be considered not significant if enacting the provisions of the proposed rule would not contribute to considerable public health concerns.
Socioeconomics and Environmental Justice	Significant	• An impact would be considered significant if there was a substantial change in job availability, including those which may result in disproportionate impacts on minorities, on a regional or national level due to management decisions to no longer grow one or more produce commodities. • An impact would be considered significant if the ability of minority populations to own and operate covered farms is disproportionately impacted. **Tribal Resources** • An impact would be considered significant if it is reasonably foreseeable that changes to the water application methods would reduce a Tribe's access to water.
	Not Significant	• An impact is not considered to be a significant impact if it results in minimal or no changes in land management practices. • An impact is not considered to be significant if there are no disproportionate impacts on the ability of minority populations to own and operate covered farms or if there is not a substantial change in job availability.
Human Health and Safety	Significant Adverse	• Adverse impacts will be considered to be significant when human exposure to chemicals through secondary routes of exposure, e.g., contaminated surface waters, occurs at levels sufficient to result in unreasonable adverse health effects. • Impacts will also be considered to be significantly adverse when there are readily identifiable increases in worker exposure to agricultural chemicals applied to covered farms. • Impacts will also be considered to be significantly adverse if they increase the risk of serious adverse health consequences or death from foodborne illness outbreaks resulting from produce.
	Significant Beneficial	• Provisions that are likely to minimize the risk of serious adverse health consequences or death from covered produce will have a significantly beneficial impact on human health and safety.
	Not Significant	• An impact will not be significant if the chemical exposures to workers or the general public is not likely to result in adverse public health impacts.

Each impact threshold will be applied to the analysis provided in this chapter. As previously stated, resource components where no significant effects have been identified are noted and excluded from further analysis.

Resource components not included for review in the EIS

FDA considered what environmental impacts, by resource component, could be excluded from analysis in this EIS. FDA does not need to consider environmental impacts in this EIS under the following circumstances: 1) where the environmental impact would not be an "effect," within the meaning of 40 CFR 1508.8, of the PS PR, if finalized, and therefore not subject to NEPA; or 2) where FDA determines the environmental impact is an "effect" otherwise subject to further review under NEPA, but the impact is not significant. For each of the following resource components, FDA determined one of these circumstances was met. Therefore, FDA is removing cultural resources, land use, and threatened and endangered species from review in this Final EIS.

Cultural Resources: The affected environment and baseline information for Cultural Resources is reported in Chapter 3.6. In regard to the cultural value of farms, the cultural value lies in the historic value of the land and any structures thereon and the lifestyle of the farm. The association of the land with a farm will not change *per se* if the PS PR were finalized, even if management decisions at the individual farm or business level may result in different applications of, for example, agricultural water or soil amendments. Farming as an industry is inherently a progressive endeavor requiring that operators be willing to embrace change (i.e., new technology) in order to remain competitive in a globally changing market. These farms have already been altered in terms of managing agricultural commodities, buildings and machinery; therefore, the additional requirements and changing practices that may necessarily result from any produce safety final rule are in keeping with other changes and modernizations that farms have made over time. Subsistence farmers, and those using more traditional farming methods, are operations that are small in nature and often grow enough food to feed themselves. To the extent such farms have produce sales below $25,000, these types of farms would not be subject to the requirements of the PS PR, if finalized. Overall, the lifestyle of the farm will not change as a result of finalizing the provisions of the PS PR because the changes that may occur will center on modifications due to safety, not in modifications to farming as a way of life.

Land Use: For purposes of the EIS, we use the term "Land Use" to refer to real property classifications that indicate either natural conditions or the types of human activity that occur, or are permitted to occur, on a land parcel. There is no nationally recognized convention or uniform terminology for describing land use categories. Land use is a planning terminology that is used on the local government level, generally in the form of planning or zoning ordinances. As a result, the meanings of land use descriptions and definitions vary among local jurisdictions. Agriculture is often coded or zoned differently from jurisdiction to jurisdiction; therefore, it cannot be examined on a nationwide, regional, or even state-level basis within the scope of this EIS. Furthermore, there are no government plans associated with the proposed action to re-zone or re-classify agricultural lands; it would be highly speculative to assume that if any farm or business loses its ability to operate due to implementation of the proposed action, it would be re-zoned as another land use. It would also be highly speculative to assume how many such businesses may lose their ability to operate, and where they are located. The proposed rule, if finalized, would

establish a series of exemptions or modified requirements where certain very small and small entities would be either excluded from coverage based on average monetary value of produce sold (proposed § 112.4), or would be eligible for a qualified exemption based on average monetary value of food sold and direct sales to qualified end users (proposed § 112.5). These exemptions, as well as other management decisions available to the farmer (e.g., switching to a non-covered crop or changing irrigation methods), provide farmers that are most likely to be economically impacted by the rule flexibility to avoid the loss of their land which would precede a land use change. For these reasons, FDA does not anticipate any land use impacts.

Threatened and Endangered Species: The proposed rule would require a grower of produce to monitor those areas that are used for a covered activity for evidence of animal intrusion and, if animal intrusion is evident, to evaluate whether covered produce can be harvested (proposed § 112.83). The proposed requirements do not propose any activity that may result in impacts to threatened or endangered species. In fact, the proposed requirements make clear that activity that may impact threatened or endangered species is not authorized by the proposed requirements. Any such activity would be subject to the independent authority and oversight of the USFWS.

NEPA mandates that federal agencies, "to the fullest extent possible," prepare an EIS for "major Federal actions significantly affecting the quality of the human environment." 42 U.S.C. § 4332. A "Major Federal action" includes "actions with effects that may be major and which are potentially subject to the Federal control and responsibility." 40 CFR 1508.18. The term "effects" includes direct and indirect effects "which are caused by the action." 40 CFR 1508.8. However, when the agency is not the legally relevant cause of an effect, the effect is not one the agency is obligated to consider under NEPA (see *Department of Transportation v. Public Citizen*, 541 U.S. 752, 770 (2004) ("We hold that where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered a legally relevant 'cause' of the effect.").

In the 2013 proposed rule, FDA proposed, under certain circumstances, to require monitoring of those areas that are used for a covered activity for evidence of animal intrusion, as needed during the growing season and immediately prior to harvest (proposed § 112.83). If animal intrusion was evident from observation of significant quantities of animals, animal excreta, or crop destruction via grazing, proposed § 112.83 would require one to evaluate whether the covered produce could be harvested in accordance with the requirements of § 112.112 (78 Fed. Reg. 3504 at 3587).

In the supplemental proposed rule, FDA stated that proposed § 112.83 "should not be construed to require the 'taking' of an endangered species, as the term is defined in the Endangered Species Act (ESA) (16 U.S.C. 1532(19)) (i.e., to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct)." (79 Fed. Reg. 58434 at 58463). To address concerns that the Produce Safety regulation may inadvertently promote practices that may adversely affect wildlife and animal habitat, including impacts on threatened or endangered species, we clarified, in proposed § 112.84, that:

> Nothing in this regulation authorizes the "taking" of threatened or endangered species as that term is defined by the Endangered Species Act (16 U.S.C. 1531-1544 (i.e., to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in

> any such conduct), in violation of the Endangered Species Act. This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

The supplemental proposed rule specifically referred growers of produce to the USFWS's Endangered Species Web site and the Information, Planning, and Conservation System Web site (79 Fed. Reg. 58434 at 58464). FDA further recommended that a grower coordinate with its office on any activity that could potentially affect listed species or critical habitat (79 Fed. Reg. 58434 at 58464). FDA consulted with USDA's NRCS and the USFWS to inform its thinking on this issue (79 Fed. Reg. 58434 at 58463).

To the extent a grower of produce takes an action that may impact a threatened or endangered species, such action would be subject to the independent oversight and authority of the USFWS and not an activity caused by the proposed requirements related to animal intrusion in proposed § 112.83. Consequently, the proposed requirements in § 112.83 would not be the legally relevant "cause" of the effect under NEPA should a grower undertake an action that may impact a threatened or endangered species. Therefore, the impacts would not be an "effect" within the meaning of 40 CFR 1508.8 that FDA would need to analyze in this EIS related to a final produce safety rule. Even if one considered such activity taken by a grower to be an "effect" of FDA's final produce safety rule under NEPA, compliance with the Endangered Species Act and USFWS regulations is the reasonably foreseeable action that growers would take, and actions taken in compliance with such laws should prevent the occurrence of any significant environmental impact under NEPA. Accordingly, FDA is not considering impacts to threatened or endangered species based on the proposed requirements for produce safety in the context of this EIS.

Distinct from threatened and endangered species, there may be activities a produce grower undertakes concerning wildlife generally that may be reasonably foreseeable and for which there may be no local, state, or federal regulatory oversight that would limit the scope of foreseeable actions growers might take. Thus, FDA is considering separately in this Final EIS whether there are any potentially significant environmental impacts to wildlife, generally, as a biological and ecological resource.

4.1 No Action: Do Not Implement a Final Rule

The No Action Alternative is assessed as a means for comparison of environmental impacts to the FDA's proposed action and corresponding alternatives. The No Action Alternative is presented in Chapter 2.1. Baseline conditions that are used to assess the No Action Alternative are discussed in Chapter 2.1, throughout Chapter 3, and as part of potential management decisions that are discussed throughout Chapter 4. Important aspects of existing, ongoing, environmental conditions discussed in the No Action Alternative are further assessed as part of the cumulative impacts analysis in Chapter 5. The ongoing conditions, for example, land subsidence and groundwater drawdown, are not the effect of agriculture alone; rather, these effects result from many influences including agricultural production, residential and commercial development, and oil and gas exploration.

FDA does not consider a no action alternative to be a viable alternative. Under the No Action Alternative, FDA would rely on our understanding of current agricultural practices, including agricultural processes implemented based on existing FDA guidance such as FDA's *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* (FDA's GAPs Guide) (FDA, 1998) and draft commodity-specific guidances; voluntary adoption by producers of some or all provisions of the proposed requirements; current or enhanced state and local enforcement activity to bring about a reduction of potential harm from contaminated produce; and risks of financial liability based on the tort system, with litigation or the threat of litigation serving to bring about the goals of the PS PR voluntarily. However, section 105(a) of FSMA (21 U.S.C. 350h(a)) requires FDA to conduct rulemaking establishing minimum science-based produce safety standards.

An estimated 2.7 million cases of domestic foodborne illnesses occur annually that are attributable to produce that would be covered by the PS PR; FDA estimates that approximately $1.88 billion annually is spent on preventing illnesses associated with microbial contamination of covered produce (FDA, 2013b). If the present conditions are to continue, the total annual foodborne illnesses and associated costs are not expected to change substantially. Data reported to the CDC indicate that, between 1973 and 1997, outbreaks of foodborne illness in the United States associated with produce increased both in absolute numbers and in proportion to all reported foodborne outbreaks (Sivapalasingam et al., 2004). Marketing agreement programs with food safety provisions, and the USDA's GAP program, which verifies conformance with FDA's GAPs Guide, have established voluntary measures to help prevent foodborne illness.[2] However, each year, about 48 million Americans (1 in 6) get sick; 128,000 are hospitalized; and 3,000 die from foodborne diseases, according to estimates from the CDC (78 Fed. Reg. 3504 at 3506). Produce farm participation in marketing agreements and the USDA GAP&GHP program would continue to provide some measure of increased food safety procedures, but it would be highly speculative to try to quantify if (or how many) farms may enroll in such programs and the extent to which such participation might change the incidence of foodborne illness.

Under the No Action Alternative, no changes are anticipated with respect to the current practices of how farms/businesses are managed. Restrictions, regulations, or guidelines (e.g., state regulations, state nutrient management plans, or private marketing and cooperative agreements) that are in place now and govern how farms apply certain food safety measures would continue to be implemented as they are today. Examples of such safety measures include controls of irrigation water quality, how and when soil amendments are applied and in what particular quantities, and certain food-safety-related management decisions about how crop harvests are managed and timed.

The current conditions would prevail with respect to produce production, and are expected to continue into the future. In addition to the continued persistence of human health risks associated with taking no action, farming practices have an impact on other aspects of the environment.

[2] Such programs do not contain enforceable requirements or requirements at the same level of public health protection as would the PS PR, if finalized.

Based on FDA 2014 estimates in the supplemental PRIA, 35,503 farms, or 1.70 percent of total U.S. farms, would be covered by the PS PR, which represents an estimated 18.7 percent of all produce-growing farms (FDA, 2014b).

Water Resources- Based upon currently available information, water quality and availability are already experiencing significant adverse effects from agriculture. These issues are addressed in Chapters 1.9 and 3.1.2, and are summarized below. Under current conditions, states that experience the highest total irrigation water supply withdrawals (Figures 3.1-12 and 3.1-13) and that grow the highest concentrations of covered produce are California, Idaho, Texas, Oregon, Arizona, Florida, Washington, and New Mexico—corresponding to regions A, B, C, D, I, J, and U (compare Figure 1.7-4 with Figures 3.1-12 and 3.1-13). These regions account for more than 80 percent of covered produce grown in the U.S. The highest groundwater withdrawals that are currently occurring in states where covered produce is grown are in California, Idaho, Texas, Oregon, Arizona, and Florida (regions A, B, C, D, I, J, and U) (compare Figure 1.7-4 with Figures 3.1-12, 3.1-23 and 3.1-24). In particular, California, Idaho, Texas, and Arizona (regions B, C, D, I and J) are located in areas where average annual precipitation typically is 20 to 30 inches, which is insufficient to support crops without supplemental water (see Chapter 3.1.3.8). Additionally, region U is presently experiencing significant drawdown effects despite a much higher precipitation and aquifer recharge rate as compared to regions B, C, D, I, and J (see Chapter 3.1.3.11). Therefore, regions important for groundwater drawdown in this EIS are considered to be regions B, C, D, I, J, and U, as well as areas in the northeastern and northcentral reaches of Mexico that share an aquifer with regions D, I, or J (see Chapters 3.1.3.7 and 3.1.3.11).

Under the No Action Alternative, the risk to water resources would continue as it is today or could potentially get worse during drought conditions when there is less surface water flow to dilute bacterial concentrations. In addition to problems such as desertification, salinization, and erosion that affect irrigated areas, the problem of downstream degradation of water quality by salts, agrochemicals, and toxic leachates is a serious environmental problem. In particular, regions that grow covered produce and that are already experiencing high exceedances in state surface water quality levels based on CWA Section 303(d) requirements (33 U.S.C § 1313(d)) (compare Figure 3.1-15 in Chapter 3.1.3.9 to Figure 1.7-4 in Chapter 1.7) and groundwater quality impairments (primarily from coliform bacteria) include regions A, B, C, L, R, T, and U (compare Figures 3.1-16 and 3.1-17 in Chapter 3.1.3.9 to Figure 1.7-4).[3] Significant current and ongoing adverse impacts such as reduced water availability, water-table declines, soil subsidence and increased costs for finding and maintaining access to water, resulting from groundwater withdrawals are presently experienced in the west and southwest in regions B, C, D, I, J, and in region U (see Chapter 3.1.3.8).

The major impacts on surface and groundwater to which current agricultural practices contribute at a national level are described in Table 4-3. Chapter 3.1 provides information showing the location of detection of nutrients, pathogen indicator organisms and pesticide or pesticide breakdown products. Under the No Action alternative, produce growing practices are expected to continue under the current paradigms.

[3] Regions A, B, C, L, R, T, and U represent the majority of the east and west coast states.

Table 4-3. General water-related environmental impacts associated with agricultural practices

Agricultural activity	Surface water	Groundwater
Tillage/ ploughing	Sediments carry phosphorus and pesticides adsorbed to sediment particles; reduction of light penetration into the water column; siltation of river beds and loss of habitat, spawning ground, etc.	None
Fertilizing	Runoff of nutrients, especially phosphorus, leading to eutrophication causing taste and odor in public water supply, excess algal growth leading to deoxygenation of water and fish kills	Leaching of nitrate to groundwater; excessive levels are a threat to public health
Manure spreading	Carried out as a fertilizer activity; spreading on frozen ground results in high levels of contamination of receiving waters by pathogens, metals, phosphorus and nitrogen leading to eutrophication and potential contamination	Contamination of groundwater, especially by nitrogen
Pesticides	Runoff of pesticides leads to contamination of surface water and biota; dysfunction of ecological system in surface waters by loss of top predators due to growth inhibition and reproductive failure; public health impacts from eating contaminated fish. Pesticides are carried as dust by wind over very long distances and contaminate aquatic systems thousands of miles away (e.g. tropical/subtropical pesticides found in Arctic mammals).	Some pesticides may leach into groundwater causing human health problems from contaminated wells
Irrigation	Runoff of salts leading to salinization of surface waters; runoff of fertilizers and pesticides to surface waters with ecological damage, bioaccumulation in edible fish species, etc. High levels of trace elements such as selenium can occur with serious ecological damage and potential human health impacts.	Enrichment of groundwater with salts, nutrients (especially nitrate)
Feedlots/ animal corrals	Contamination of surface water with many pathogens (bacteria, viruses, etc.) leading to chronic public health problems. Also contamination by metals contained in urine and feces.	Potential leaching of nitrogen, metals, etc. to groundwater

Biological and Ecological Resources- The clear cutting of land for agricultural purposes historically has impacted local wildlife and vegetation by appropriating habitat for agricultural purposes. Vegetation types vary by region. Nationally, there are thousands of species of native, non-native, and invasive plants that play important roles in providing habitat and fulfilling life requisites for wildlife species. On a national level, this vegetation is varied and includes hedgerows, large forest corridors, wet meadows not suitable for agriculture, and buffers adjacent to stream channels and lakes. Wildlife species (mammals, birds, fish and other aquatic organisms, amphibians, reptiles, and invertebrates) are important participants in the web of life, fulfilling roles necessary for healthy and successful ecosystems. Many of these species are protected by a patchwork of federal, state, and local laws designed to manage the overall environmental health and economic sustainability of wildlife resources. Because most wildlife species are mutually reliant and interdependent on other species within the ecosystem, the health of the entire system is important. Crop production not only removes habitat but also has the potential to expose wildlife to diseases present in domesticated animals as well as to animal waste and chemicals that enter the

environment as a result of farming practices. Historically, agriculture, through the prior practice of converting wetland to farmland, has also resulted in a net loss of wetlands nationwide due to filling and draining of wetlands. Current laws and the requirement for permits have slowed the conversion of wetlands for other uses such as agriculture and industrial, institutional, or residential development. Wetland permits often include conditions such as mitigation for wetland loss. Mitigations may include replacement or enhancement.

Over the years, conservation measures have been established to help minimize habitat impacts. The omnibus bills which collectively are generally referred to as Farm Bills, first passed in the 1930s, have helped to mitigate these and other environmental impacts through the establishment of voluntary conservation programs that help to protect wildlife habitat, control soil erosion, and reduce runoff. The Agricultural Act of 2014 (or the 2014 Farm Bill) (Pub.L.No. 113-79, 128 Stat. 649) takes several existing conservation programs, including the wetlands reserve program, which allows the restoration, maintenance and protection of wetlands on private property, and the grasslands reserve program, which enables the restoration of native grasslands, and consolidates them into the Agricultural Conservation Easement Program. Activities covered under the Farm Bill that are aimed at conservation include the Conservation Reserve Program, which pays farmers to set aside marginal land and helps fund activities on these land such as planting of native grasses or establishing erosion control measures; the Conservation Stewardship Program, which rewards the use of environmentally friendly agricultural practices; and the Environmental Quality Incentives Program, which provides technical and financial assistance for the implementing of conservation practices on farms and ranches. Participation in these programs is voluntary.

Soils- Soil provides essential ecosystem services that are critical for life and is the basis of our nation's agroecosystems, which provide us with livestock feed, fiber, food and fuel (SSSA, 2010). However, maintaining healthy soils demands care and effort because farming disrupts the natural soil function. Farming disturbs the natural processes of soil, including that of nutrient cycling (i.e., the release and uptake of nutrients) (FAO, 2005). A major impact of agriculture on soil has been the quality and quantity of soil organic matter (SOM) (see Chapter 3.3.3.6). Specifically, the loss of soil organic carbon (SOC) has been attributed to cultivation with losses of 50 percent being common (see Chapter 3.3.3.4) (University of Minnesota Extension, 2009).

Agricultural practices contribute to the depletion of SOC through deforestation and biomass burning, drainage of wetlands, tillage, crop residue removal, summer fallow, cultivation, and overuse of pesticides and other chemicals. Cropland soils generally store less SOC than grazing land because cropland has greater disturbance from cultivation, a lack of manure being returned to the system, less root biomass, and less biomass returned to the soil surface. This loss of SOC from agricultural soils has resulted from many factors such as climate and soil type, tillage intensity and depth, crop rotation decisions, organic matter inputs, amount of plant residue on surface, soil biological activity, length and time of fallow, and erosion (University of Minnesota Extension, 2009).

Given the declining trend in total agricultural acres, environmental impacts are not projected to exceed those described in Chapter 3.3.

Waste Generation, Disposal, and Resource Use- USDA NASS data (2001, 2002, 2007, and 2012) show a declining trend in the use of untreated BSAs of animal origin and chemical fertilizers (Chapter 3.1.3.1, Table 3.4-1).

This downward trend in the use of chemical fertilizers suggests there is an increasing trend in the use of other, more environmentally beneficial practices, such as the use of green manure or cover crops. This trend could also be the result of more growers complying with state nutrient management plans (see Chapter 3.4.2), which enable growers to use these resources more efficiently.

Although BSAs of animal origin are not the primary source of nutrients applied to covered produce crops, they are an important nutrient source, and there are often close local relationships between manure generating farms (e.g., AFOs and CAFOs), commercial manure brokers/suppliers, and covered produce growers (see Chapter 3.4.3.1).

Farms using the resource

Of the estimated 35,503 farms that would be covered farms as defined in the PS PR, an estimated 4,438 farms (12.5 percent) used BSAs. Of the 4,438 covered farms using BSAs, an estimated 821 farms (18.5 percent of farms using BSAs, or 2.3 percent of all covered farms) used untreated BSAs (raw manure), while an estimated 3,618 farms (81.5 percent of farms using BSAs, or 10.2 percent of all covered farms) use treated BSAs (composted manure). The remainder of covered farms (approximately 87.5 percent) may use chemical fertilizers, green manure or cover crops or BSAs of other origin, such as plant or mushroom (see Chapter 2.1, subpart F and Tables 2.1-3 and 2.1-4).

FDA identified eleven regions where the proposed application interval for BSAs of animal origin are likely to impact growers of covered produce. These regions represent the largest potential for changes in handling requirements for BSAs of animal origin: A, B, C, D, J, M, L, P, S, U and V (See Figure 3.4-1).

Related infrastructure

Facilities that may store raw manure and that may perform composting operations (e.g., CAFOs) are sometimes required to apply for a NPDES permit (Chapter 3.4.2). As discussed in Chapters 3.1.2, 3.4.2, 3.4.3.5, NPDES permits set controls on water pollution by regulating point sources[4] that discharge into surface water bodies, and are effective for meeting state water quality criteria, which are required under the CWA and most often are managed by the states. Adherence to NPDES permits are generally required when there is the potential to release pollutants such as nitrogen and phosphorus, organic matter, sediments, pathogens, heavy metals, hormones, antibiotics, and ammonia to the environment. The provisions of a facility's NPDES permit can be protective of drinking water as well as primary contact recreation (such as for swimming), fish consumption and aquatic life support.

[4] Point sources are usually associated with industrial, municipal, or other facilities that discharge water into a surface water through pipes, ditches, or conveyances. More information may be found here: http://water.epa.gov/polwaste/npdes/.

Therefore, if the facilities are operated and maintained in accordance with their permits, under normal circumstances there are processes in place to protect against adverse harm to the environment (i.e., effects from runoff). It may be noted that significant amounts of rain, for example, may contribute to unintentional discharges to receiving waters.

Air Quality and Greenhouse Gases- Agriculture is an important source of emissions of air pollutants and greenhouse gases (also written as GHGs). These emissions can affect local and regional air quality (e.g., PM, pathogens) and also contribute to problems caused by GHG emissions on a national or global scale. The most important agricultural emissions in the U.S. include $PM_{2.5}$, PM_{10}, methane, nitrous oxide, and ozone precursor gases. Additionally, agriculture also consumes fossil fuels for farm operations, thus emitting carbon dioxide (CO_2), nitrogen oxides (NO_x), volatile organic carbons (VOCs), and particulates (Aneja et al., 2009).

Of the six criteria air pollutants for which EPA has developed NAAQS, PM emissions are most directly associated with agricultural practices. According to data from the EPA, 896,727 tons of $PM_{2.5}$ and 4,502,018 tons of PM_{10} were released in the U.S. in 2011 from agriculture, mostly as a result of crop and livestock dust emissions (EPA, 2014i).[5] Agriculture is a major contributor to emissions of PM_{10}, which is typically directly emitted to the atmosphere by actions such as tillage operations, harvesting, road travel, animal movement, and wind erosion. Although $PM_{2.5}$ can also be directly emitted, a significant portion of fine particulate matter is formed in the atmosphere by chemical reactions with precursor gases (e.g., NOx, VOCs, ammonia (NH_3)) that may result from engine use, fertilizer application, and animal operations (USDA NRCS, 2012a). Agriculture also indirectly contributes to ground-level O_3 formation through emissions of ozone precursor gases (i.e., NOx, VOCs) from a variety of activities including manure decomposition, soil processes (nitrification and denitrification), and combustion from farm equipment (USDA NRCS, 2012b).

Agricultural activities contribute directly to emissions of greenhouse gases through a variety of processes. In 2012, agricultural GHG sources accounted for approximately 10 percent of total U.S. GHG emissions (Figure 3.5-8) (EPA, 2014k). Although CO_2 accounts for over 80 percent of U.S. GHG emissions, methane (CH_4) and nitrous oxide (N_2O) are the primary greenhouse gases emitted by agricultural activities (USDA CCPO, 2011). Agriculture made up 38 percent of total U.S. CH_4 emissions in 2012 and 83 percent of total N_2O emissions (see Figure 3.5-9) (EPA 2014k). Between 1990 and 2012, methane emissions from agricultural activities increased by 13.6 percent, while nitrous oxide emissions had an overall increase of 9.5 percent. The primary GHG sources for agriculture include N_2O emissions from cropped and grazed soils, CH_4 emissions from ruminant livestock production and rice cultivation, and CH_4 and N_2O emissions from managed livestock waste. Agricultural soil activities such as fertilizer application produced approximately 74.8 percent of N_2O emissions in the U.S. in 2012. Enteric fermentation was the largest source of CH_4 emissions in the U.S. in 2012, at 141.0 Tg CO_2 Eq. Overall, emissions from manure management (includes CH_4 and N_2O) increased 54.7 percent between 1990 and 2012 (EPA, 2014k).

[5] The EPA data apply to agriculture as a whole, and according to the USDA NASS survey data available for the same time period the agricultural community consists of 2,109,303 farms nationwide. The PS PR covers a much smaller subset of farms, 35,503 farms nationwide. Therefore, we can expect that PM related impacts associated with this smaller subset of covered farms would also be much smaller than nationwide PM dust emissions.

Energy use represented approximately 8 percent of the total GHG emissions from the agricultural sector in 2012 (see Figure 3.5-13) (EPA, 2014k). Farm operators rely on a variety of energy sources to perform agricultural practices. For example, large amounts of diesel fuel, gasoline, and liquefied petroleum (LP) gas are used for field operations during crop production (USDA CCPO, 2011). Irrigation systems that use pumps to distribute water also use energy. In 2008, approximately 49 million acres of U.S. farmland were irrigated with pumps powered by liquid fuels, natural gas, and electricity (USDA CCPO, 2011). According to the EPA, 2012 electricity-related emissions were responsible for approximately 62.2 Tg CO_2 Eq. of the 676.3 Tg CO_2 Eq. total GHG emissions from the agricultural sector, representing only three percent of the total GHG emissions attributed to the electric power industry as a whole in 2012 (EPA, 2014k).

Under the No Action Alternative, no changes in how farms and associated livestock operations are managed are anticipated. Therefore, current trends to air quality and greenhouse gases resulting from these practices are expected to continue.

Socioeconomics and Environmental Justice- Under the No Action Alternative there would be no added costs to the produce industry (see Chapter 1.9). Industry would continue to operate based on existing practices and could continue to rely on current guidance from FDA and USDA, as well as state and industry standards under marketing agreements. The cost of complying with existing marketing agreements has already been absorbed by the industry. It is possible that new marketing agreements will be developed or existing marketing agreements revised. However, it is not possible to predict future actions. At this point, FDA has not been made aware of any such development or revision of existing marketing agreements.

There would be no change in socioeconomic impacts associated with the No Action alternative, as current conditions would continue.

Environmental Justice

Minority Groups: As discussed in Chapters 1.9 and 3.7.3, with respect to Environmental Justice impacts related to the PS PR, FDA considers potential impacts to minority principal farm operators and farmworkers. USDA NASS survey data provides information on principal operators of farms. The USDA ERS, DOL, and the BEA provide data on farm employment. USDA NASS survey data further provides information on farmworker income levels. The DOL also reports data on farmworkers in terms of ethnicity and income; however, state-level data are reported only for California. In addition, farmworker employment is often seasonal (USDA ERS, 2014a).

In the Non-Contiguous States, 59.0 percent of principal farm operators identify themselves as minorities. Under CEQ guidance, *Environmental Justice Guidance under the National Environmental Policy Act* (1997a), a minority population is found to exist where the minority population of the affected area exceeds 50 percent of total population. Given that the percent that have identified themselves as minorities exceeds the threshold established in the CEQ guidance, for the purpose of this analysis farm operators in non-contiguous states are considered a minority population. The non-contiguous states are Alaska and Hawaii, which are regions W and V, respectively, for the purpose of the EIS.

Additionally, under CEQ guidance, a minority population is found to exist where the minority population percentage of the affected area is meaningfully greater than the minority population percentage in the greater population or other appropriate unit of geographic analysis. The national average of farms with minority principal operators is 10.5 percent. As described in Chapter 3.7.3, by applying an additional 10 percent to this national average FDA establishes a "meaningfully greater" threshold of approximately 11.6 percent. Of the regions included within the analysis, besides regions W and V, other regions that have a population of minority principal operators greater than the 11.6 percent threshold are regions A, B, C, and D. Thus, the analysis of environmental justice impacts on minority principal operators is limited to regions A, B, C, D, W, and V.

Based on the information on farmworkers reported by the DOL through surveys taken by that agency (see Chapter 3.7.3), regions where there are potentially populations of minority farmworkers that may be impacted by the rule, if finalized, include regions C, D, I, and J. The limited information reported by the DOL, however, only provides farmworker income-related information for region C.

Given that current conditions would continue, there would be no significant impacts on minority principal farm operators under the No Action Alternative.

Low-Income: For the purposes of this EIS, low-income persons include any persons whose median household income is at or below the HHS poverty guidelines. While the 2014 HHS poverty threshold data is available, the 2012 dataset is the appropriate data set for a comparison with the 2012 USDA ERS data. Chapter 3.7, Table 3.7-17 identifies the 2012 HHS poverty guidelines for the 48 contiguous states and the District of Columbia. The 2012 HHS poverty guidelines are also published in 77 Fed. Reg. 4034 (January 22, 2012).

An area is identified as containing a low-income population when the median household income for the area is below the HHS poverty threshold, which was determined to be $23,050 for a family of four in 2012.[6]

There would be no significant impacts associated with the No Action Alternative, as current conditions would continue.

Human Health and Safety- FDA has extensively analyzed the current effects of foodborne illness as part of the rulemaking process. Those discussions are summarized in Chapters 1, 2, and 3.8, as well as at the beginning of this section. Assuming current practices continue, FDA anticipates that there would be a significant continued risk to public health under the No Action Alternative.

FDA received a comment on the Draft EIS expressing concern that the EIS did not acknowledge potentially adverse health impacts to farmworkers from an increased use of chemical inputs. The following text regarding chemical fertilizers and pesticides is provided to establish the baseline conditions for the use of such chemicals on farms. Where necessary, we made additional edits to Chapter 4 in an effort to fully address the commenter's concern.

[6] http://aspe.hhs.gov/poverty/12poverty.shtml

There are additional adverse impacts associated with agricultural practices in the areas of worker safety as well as secondary exposure to agricultural chemicals (primarily those that enter the water supply through runoff or improper application). These problems occur nationwide.

In 1997, the EPA initiated an effort to examine potential harmful effects on public health and the environment from contaminants in fertilizers. As such, EPA's Office of Solid Waste undertook an assessment of the risks from heavy metals and other contaminants in fertilizers. The *Estimating Risk from the Use of Agricultural Fertilizers* report (*Estimating Risk* Report) presents the findings of that risk assessment (EPA, 1999c).

The *Estimating Risk* Report analyzed the risks to human health from macronutrient fertilizers (NPK), micronutrients (e.g., zinc), and other agricultural soil amendments. Thirteen types of fertilizer products, applied to agricultural fields and home gardens at recommended application rates and frequencies, were assessed.

A probabilistic approach was used to estimate increase in lifetime cancer risk and/or non-cancer health effects associated with exposure to the potentially hazardous constituents contained in fertilizer and other soil amendments.[7] Crystal ball®, a software program, was used to perform toxicity modeling and simulation. Data that EPA used was taken from published reports and models, across a range of factors including geographic location and meteorological parameters, crop types, plant uptake factors, and soil conditions.

The assessment used resident farmers and their children as receptors within EPA's risk assessment model, given that these receptors would have the highest exposure out of the general population. The assessment considered exposure through the following pathways:

- Direct ingestion of fertilizer products during fertilizer application,
- Ingestion of soil amended with fertilizers,
- Inhalation of particles and vapors in the air during and after fertilizer spreading and tilling,
- Ingestion of plant (fruits, vegetables, grains and forage) and animal products (fish, beef and dairy) produced on soil amended with these products, and
- Ingestion of home-caught fish from streams located adjacent to fertilizer-amended fields.

The evaluation did not include a comprehensive evaluation of ecological risks. However, ecological risks were evaluated by comparing concentrations of metal and dioxins predicted to be washed into adjacent streams to the EPA's ambient water quality criteria.

Based on the assessment of 13 types of fertilizer products, EPA found that hazardous constituents in fertilizers generally do not pose harm to human health or the environment. However, a few fertilizer products had contaminant levels high enough to potentially cause cancer risk or non-cancer hazard of concern. Other than these exceptions, which may or may not still be on the

[7] A probabilistic approach is an approach that enables variation and uncertainty factors in order to obtain more realistic results (as compared to a deterministic approach, in which factors such as toxicity are fixed, but impacts may not be applicable or adaptable to all real-world conditions where the risk of exposure is variable).

market, contaminant levels found in the fertilizer products analyzed as part of this assessment are not expected to cause risks of concern. No exceedances of water quality criteria were projected.

With respect to the use of chemical pesticides, FIFRA mandates that EPA regulate the use and sale of pesticides to protect human health and preserve the environment. There is the possible risk of chemical exposure to site workers that may have to handle pesticides prior to application, but these risks are minimized when using proper handling techniques including using recommended personal protective equipment in accordance with labeling requirements or product recommendations (e.g., chemically resistant gloves to avoid exposures that may otherwise cause unreasonable health effects) as described by the manufacturer. In addition, EPA established the Worker Protection Standard to reduce the risk of pesticide poisoning and injury among agricultural workers including those that handle pesticides (40 CFR 170.1). The standard further requires that agricultural establishments protect [its] workers from pesticide exposure, to train workers about pesticide safety, and to provide mitigation measures if exposures were to occur. EPA mandates aspects of the worker protection standard such as training frequency, increased signage where pesticides are applied to reduce exposure until residues decline to a safe level, and by imposing age requirements on pesticide handling (EPA, 2014n).

Farmworker protection is also addressed by Section 5(a)(1) of OSHA (General Duty Clause), which states that employers should supply employees a workplace free of recognized hazards that are likely to cause death or serious harm and should comply with all OSHA standards, and that employees should also comply with all OSHA standards applicable to their own actions and conduct. Farms are subject to OSHA under 29 CFR Part 1910, Occupational Safety and Health Standards for Agriculture under 29 CFR Part 1928, and the General Duty Clause.

FDA does not consider the misuse of pesticides to be reasonably foreseeable for various reasons related to farm operations. The misuse of pesticide by over application could potentially lead to crop losses, soil degradation, and other unforeseen effects, which in turn would further result in economic impacts to the farmer (Aktar et al., 2009; USDA NRCS, 2013a). Moreover, the EPA, which regulates water quality, issues guidance documents for control of pesticides potentially entering the waters of the United States (EPA, 2015). The states' department of environment or other water quality governing departments place further regulations on pesticide application for which pesticide applicators must receive a permit, certification or license. The person(s) applying the pesticides must follow these regulations, either after obtaining a license/certification or under the supervision of someone possessing these certifications (FIFRA, 7 U.S.C. § 136a(d)(1)(C)(ii)). Therefore, due to potential fines or restrictions placed on the pesticide applicator, it is reasonably foreseeable that the application of pesticides with agricultural water will be done in accordance with federal and state guidelines, along with the individual pesticide label recommendations for application. Further, pesticides can be costly; therefore, it is unlikely that a farmer will purchase and apply more pesticide product than what is necessary to operate their farm.

Therefore, when following the prescribed handling procedures associated with product labeling requirements, including using recommended personal protective equipment (e.g., chemically resistant gloves to avoid exposures that may otherwise cause unreasonable health effects), adhering

to the provisions of the worker protection standard, and by remaining in compliance with OSHA regulations, the risk to farmworkers from chemical exposure is minimized.[8]

With respect to populations that may be exposed to pesticides in their drinking water, consumers of municipally treated water receive a drinking water quality report annually that identifies compounds found in their drinking water. Municipally supplied water is treated for pesticides at the local water treatment facility based on standards set by EPA and the SDWA. However, antimicrobials are often added to public water supplies in order to disinfect drinking water from harmful microbes.

For those consumers that do not receive municipally treated water (e.g., consumers using well water, cisterns, or spring water), EPA recommends that their water supply be tested regularly, and if found to be contaminated with pesticides should be subjected to corrective action (e.g., water treatment, use a different water source, use bottled water).[9] The federal government does not regulate private drinking water wells; however, some state and local governments do set standards on water source quality including for private wells. Additional information on testing for private drinking water sources, keeping drinking water safe, and corrective actions if water sources are found to have potentially unsafe levels of contaminants may be found at EPA's Web site for Private Drinking Water Wells.[10] It should be noted that EPA's product registration process and requirements for manufacturers to include in their product labeling (e.g., proper use, handling, and disposal) are designed to protect from harm both the user of the chemical as well as the public at large.

No Action Conclusion

If the agency takes no action, it is possible that additional marketing agreements will be established to try to prevent foodborne illness resulting from pathogen contamination of a specific commodity or group of commodities. Such marketing agreements may establish stringent standards that could increase the use of pesticides, alter BSA application, or result in other changes that would result in increased exposure to workers or potentially—through secondary routes—to the general public. However, as previously stated under this alternative, FDA is not aware of any future marketing agreements that are in development or under revision. Therefore, it would be speculative to try to determine what impacts, if any, would result.

In light of the impact analysis that is conducted in Chapters 4.4 through 4.7 and the potential for a range of minor to significant adverse environmental impacts, FDA considers the No Action Alternative to be the environmentally preferable alternative.

[8] The proper use and handling of such chemicals is a reasonably foreseeable use because of the mandates in place for farmers to follow in terms of worker protection, as well as the protective measures (e.g., equipment, gloves) that are widely available. More information on the safe use, handling, storage, and disposal of pesticides can be found here: http://www2.epa.gov/agriculture#Hazards/SafeUse.

[9] More information may be found at EPA's drinking water and pesticides Web site: http://www2.epa.gov/safepestcontrol/drinking-water-and-pesticides.

[10] http://water.epa.gov/drink/info/well/index.cfm.

4.2 Subpart E: Standards Directed to Agricultural Water

Water has been shown to be a possible route of pathogen contamination in the field and after harvest. While produce outbreaks citing contaminated water as a suspect vehicle in foodborne disease are plentiful, conclusive evidence is rare (Solomon and Matthews, 2006; WHO, 2006) due to time and resource constraints related to field evaluations, collections, and analytical work coupled with the often-transient nature of circumstances leading to contamination. Potential contributing factors cited in produce-associated outbreaks where water was identified as the likely source of contamination include run-off from nearby animal pastures and feed lots, cracked or damaged wells, floods, raw sewage infiltration, and surface waters contaminated with feces (Berger et al., 2010). Studies have demonstrated that pathogens can be transferred from contaminated water to produce (Ijabadeniyi et al., 2011). The presence of bacteria in irrigation surface waters is dynamic, often showing seasonal variation due to changes in temperature, precipitation, and animal carriage rates that may ultimately influence human exposure to waterborne pathogens. For example, one research paper correlated the number and diversity of *Salmonella* serotypes isolated from a mixed use watershed (irrigation, swimming, fishing) in southern Georgia to summer seasonal temperature/rainfall patterns and coincident with salmonellosis case reports (Haley et al., 2009). Pathogen survival rates in water are affected by many of the same parameters affecting survival rates in soil, i.e., UV exposure, temperature, nutrient availability, competition, and pH among others. However, some pathogens (e.g., *Salmonella*) appear to be better adapted for long term aquatic survival than others (e.g., *Shigella*) (McElhany and Pillai, 2011).

Groundwater has been historically viewed as less likely to be contaminated with human pathogens than surface water because of the natural filtering capacity of soil and the depth bacteria and pathogens would have to travel to compromise its source. As a general rule, deeper wells filter out more bacteria and pathogens than shallower counterparts given similarly structured soils and other geological properties. However, groundwater can be contaminated with pathogens by infusion of wastewater, failed septic tanks, landfill leaks, and improper management of animal wastes. Although wells that are properly constructed and appropriately situated are generally less vulnerable to contamination compared to surface water sources, private wells are an additional concern as routine monitoring and regular treatment are rare (Reynolds et al., 2008). Studies have found that (1) 11 percent of U.S. groundwater sites from 20 states are reported to have tested positive for *Cryptosporidium*, *Giardia* or both (Moulton-Hancock et al., 2000); and (2) in a 12-year (1991-2002) survey of waterborne diseases, of 183 documented outbreaks associated with drinking water, 76 percent were from a groundwater source (Reynolds et al., 2008). Moreover, direct leaching of *E. coli* and *Campylobacter* into shallow groundwater sources has been demonstrated (Close et al., 2008). Figure 3.1-17 in Chapter 3.1.3.9 shows the locations of U.S. principal aquifers that tested positive for fecal-indicator bacteria (USGS, 2006b).

In addition to water source and quality, the type of irrigation system or method of use may influence the likelihood of pathogen contamination of produce. For instance, Mitra et al. (2009) showed that *E. coli* O157:H7 survived longer on leaf surfaces of spinach when introduced via water droplets than on roots when introduced by soil infiltration. However, the opposite relationship was demonstrated in the case of *Campylobacter jejuni* in spinach and radish, where survival rates in root systems were significantly higher than on leaves (Brandl et al., 2004). These

findings suggest that pathogen survival rates may be dependent not only on mode of introduction (in this case, type of irrigation system), but also on specific pathogen-commodity interactions.

For this reason, Subpart E provides "science-based minimum standards directed to agricultural water that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic (FD&C) Act" (78 Fed. Reg. 3504 at 3559).

Management decisions

The environmental impacts of standards directed at agricultural water are the result of the management decisions a covered farm makes in order to either comply with the standard or not be subject to the standard. FDA has chosen to take a non-prescriptive approach when establishing standards to allow for, and encourage, scientific advancement in the measures available to comply with the proposed rule.

As discussed at the beginning of Chapter 4, FDA, in coordination with USDA, identified the reasonably foreseeable actions, or management decisions, that businesses potentially affected by any final rule might take in order to come into compliance with, or to potentially avoid being subject to, the proposed action or alternatives under consideration for inclusion in the final rule. Management decisions were considered reasonably foreseeable based on certain considerations, including if such decisions were in compliance with existing laws and regulations, if they would allow for compliance with the alternatives being considered, and/or if the technology is either currently available or in development and has been considered for the stated purpose. Management decisions that would be suitable options for only some covered produce were also included, even if such decisions would not be a viable option for all covered produce. As part of the comment period on the 2013 proposed rule, FDA received extensive comments from industry, many of which provided information on the potential actions that would be needed to comply with the proposed standards. Management decisions that were either explicitly stated or implied in these comments were considered. FDA also received public comment on management decisions during the Draft EIS public comment period, and FDA considered these comments in finalizing this EIS We expect that farms would use one or a combination of these decisions depending upon their individual conditions. Under subpart E, FDA and USDA identified the following actions as reasonably foreseeable management decisions in relation to the proposed water requirements or corresponding alternatives: the potential use of chemical treatment of agricultural water sources to comply with the water quality requirements, switching the irrigation method to a non-contact method, switching water sources, switching to agricultural commodities that are not covered by the rule (cease growing covered produce), and adding mechanisms to account for microbial die-off in the field and post-harvest (applies to Alternatives I, III, IV-a, and IV-c).

While all reasonably foreseeable alternatives have been identified, FDA is aware that some management decisions will likely be preferable or potentially more viable to covered farms. In its outreach on the FSMA supplemental proposed rule, FDA heard from stakeholders about the likelihood of certain management decisions, given the flexibility added to the proposed

requirements for agricultural water sources.[11] In the supplemental proposed rule, FDA added an allowance for consideration of microbial die-off in the field prior to harvest (using a die-off rate of 0.5 log per day) in order to meet the proposed agricultural water standards and an allowance for post-harvest microbial die-off and/or removal techniques, provided there is adequate supporting scientific data and information. Given this added flexibility, it is less likely that operations will need to switch water sources to meet the proposed agricultural water standards.

General background on resources related to the proposed provision

Water Resources- In order to determine the potential environmental effects of a standard directed to agricultural water, it is important to understand the source of water used for growing covered produce, whether demands on that water are sustainable, and the extent to which that water would be considered impaired for the intended use due to levels of generic *E. coli* which would require measures to bring the water into compliance with a standard established by FDA. Water quality and availability are described in Chapters 1.9, 3.1.2 and 4.1. As described in more detail below, both are already experiencing significant adverse effects as a result of agricultural activities and other influences, including those related to covered produce as well as those related to non-covered produce and other agricultural crops that are not produce commodities. Water quality and availability and their current significance status are viewed on a nationwide basis and are influenced by other factors (e.g., development); the significance of these factors is considered in the cumulative impacts analysis (Chapter 5). FDA considers impacts from actions that result in groundwater drawdown to have significant impacts in regions where current conditions for groundwater depletion have significant environmental impacts. Therefore, this chapter assesses the potential for alternatives to contribute to water quality and availability conditions where current conditions have significant impacts, relative to the potential management decision. FDA has determined that there may be no significant impacts to other regions that are not presently experiencing water quality problems, and that could potentially reasonably meet a proposed water quality standard without resulting in a substantial (e.g., region-wide) shift to other water resources in order meet a water quality standard.

Water Sources

The geographic distribution of total, surface-water, and groundwater withdrawals for irrigation is described in Chapter 3.1.3.8 and shown in Figure 3.1-13.

Water Availability

The majority of surface and groundwater withdrawals (85 percent) and irrigated acres (74 percent) were in the 17 conterminous Western states (see Chapter 3.3.1.8). The 17 Western states are located in areas where average annual precipitation typically is less than 20 inches and is insufficient to support crops without supplemental water.

Under current conditions, states that are experiencing the highest total irrigation water supply withdrawals (Figure 3.1-12) and that grow the highest concentrations of covered produce are California, Idaho, Texas, Oregon, Arizona, Florida, Washington, and New Mexico, which

[11] Transcripts from the November 13, 2014, public meeting on Supplemental Notices of Proposed Rulemaking are found at: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm418878.htm.

correspond to regions A, B, C, D, I, J, and U (regions for these States shown in Figure 1.7-4). These regions account for more than 80 percent of covered produce grown in the U.S. The highest groundwater withdrawals where covered produce is grown occur in California, Idaho, Texas, Oregon, Arizona, and Florida (regions A, B, C, D, I, J, and U). In particular, the western states of this grouping are located in areas where average annual precipitation typically is 20 to 30 inches, which is insufficient to support crops without supplemental water; these include California, Idaho, Texas, and Arizona (regions B, C, D, I, and J). Region U is presently experiencing significant drawdown effects despite a much higher precipitation and aquifer recharge rate as compared to regions B, C, D, I, and J (see Chapter 3.1.3.11). Therefore, regions important for groundwater drawdown in this EIS are considered to be regions B, C, D, I, J, and U, as well as those areas in the northeastern and northcentral reaches of Mexico that share an aquifer with regions D, I, and J (see Chapters 3.1.3.7 and 3.1.3.11). As shown in Figures 3.1-23 and 3.1-24, there are several geographical areas where large-scale groundwater depletion is evident over agricultural areas with a high concentration of covered farms.

Significant dewatering is presently evident over the Central, Coachella and Death Valleys of California; Alluvial Basins of Arizona; and the Columbia Plateau in southeastern Washington and northeastern Oregon. Because of the 2013 drought, Central Valley irrigators faced about a one-third reduction (6.5 million acre feet, or maf) in surface water deliveries during the 2013 growing season, compared with normal years (USGS, 2013b). Growers are likely to increase groundwater pumping to replace about 5.0 maf of this shortage; however, this leaves a shortfall of 1.5 maf or about 7.5 percent compared to normal irrigation water use in the Central Valley (USGS, 2014b). In 119 years of recorded history, 2013 was the driest calendar year for the state of California (USGS, 2013b).

Water Quality

Impaired Surface Waters

Information that is obtainable from the EPA impaired water database, as described in more detail in Chapter 3.1.3.9, provides data on the type and level of impairment (including impairment by pathogens, as potentially indicated by generic *E. coli*) and is based on discrete samples, the number of which vary significantly by state, with some states reporting few, if any data. As such, these data presented in Chapter 3.1.3.9 may identify some areas of possible pathogen contamination but cannot be considered to be representative of all possible sites. Nonetheless, EPA indicates that based on CWA Section 303(d) (33 U.S.C § 1313(d)) water quality standards set by states (i.e., TMDLs) and Section 305(b) (33 U.S.C. § 1315) reports, there are more than 86,747 miles of streams and rivers impaired by *E. coli*; 57,562 miles impaired by fecal coliform; 10,152 miles impaired by enterococcus bacteria; 7,349 miles impaired by other bacteria; and 4,184 miles impaired by other pathogens of the more than 3 million square miles of streams in the nation.

Impaired surface waters that are co-located with regions in which covered produce is grown are found mainly in regions A, B, C, L, R, T, and U (compare Figure 3.1-15 with Figure 1.7-4); this corresponds to the West, Northwest, Great Lakes region, Northeast, and Mid-Atlantic moving southward to the Southeast. This indicates regions where there is an increased likelihood that farmers are using waters that may require treatment to be in compliance with the water quality standard FDA decides to finalize.

Impaired Groundwaters

Based upon sampling data from the NAWQA program (USGS, 2014b) supporting groundwater quality analysis, while pathogens are less prevalent in groundwater, groundwater may still be contaminated. The groundwaters most affected by the presence of coliform bacteria were those in the Valley and Ridge, the Floridan, and the Piedmont and Blue Ridge aquifers, where more than 50 percent of the study wells tested positive for the above-noted bacteria. A positive test merely indicates the presence for the bacteria, and not an exceedance of any established water standard. These affected groundwaters are located in regions A, B, C, L, R, S, T, and U (compare Figure 3.1-17 with Figure 1.7-4) (NAWQA program; USGS, 2014b).

Impacts of Standard on Water Resources

The greatest potential for significant impacts on water resources would be expected from management decisions to use chemical or physical treatment to bring agricultural water sources into compliance with any of the alternatives' water requirements, or switch water sources. Industry has already taken steps to improve the quality of the water that is used on some commodities. As discussed in Chapter 2, voluntary (and some mandatory) marketing agreements exist for specific commodities. A component of some of these marketing agreements is standards directed at water quality. In many cases, the numeric standard is as stringent or is more stringent than what is considered in the alternatives (e.g., T-GAPS, CA and AZ LGMA). Some potentially covered farms that may already be complying with these marketing agreements are already using water that is in compliance with the standards that are under consideration. This includes many leafy green producers in California and Arizona and tomato growers in Florida (Florida T-Gaps is mandatory for tomato growers in that state), as cited above and in Chapter 2.1. Such marketing agreements help to form the background conditions that many farms potentially covered by the rule are already experiencing. The cumulative impacts of the marketing agreements and the proposed rule are also discussed in greater detail in Chapter 5. In general, the existence of these marketing agreements, particularly in produce growing regions currently experiencing water impacts, minimizes the severity of potential impacts on resource components associated with a final rule, as the number of farms that would need to alter their current management practices is less than the total number of covered farms.

Alternative IV allows for the standards considered under Alternatives I through III to include root crops that are irrigated using low-flow methods. The likelihood that any management decision would be selected for Alternative IV is considered as part of the analysis of Alternatives I through III. However, the severity of a potential impact would vary depending on whether root crops were included, as the total covered acreage would differ.

Use of Chemical Treatment to Bring Agricultural Water Sources into Compliance

Presently, there is no EPA-approved chemical treatment for contaminated water used to irrigate cropland (EPA, 2014a). While there are no pesticide products registered to treat contaminated irrigation water used to irrigate cropland, the EPA maintains a list of approximately 50 Registered Antimicrobial Products as Sterilizers (40 CFR Parts 152 and 156) that may be used to prevent fouling of pipes or for treatment of wells. Farmers who use the products for these registered uses may see some improvement in their water quality. However, these compounds are not registered to control pathogens in water applied directly to produce. The registered uses do not correspond

to the standards directed at agricultural water, and therefore, would not be an effect of the proposed rule, if finalized. Therefore, FDA is not including an evaluation of environmental impacts from such uses in the context of this Final EIS.

Registration policy documents, disinfectant technical science section documents, product information (including potential hazards related to human health, handling, storage, and environmental or ecological systems) and registration information may be found at the EPA's Web site.[12]

When considering treatment technologies for contaminated irrigation water to satisfy FDA-established qualitative or quantitative water quality standards in proposed §§ 112.41 and 112.44, water would need to be treated in accordance with proposed §§ 112.43(a) and 112.44(b) and (c). Treatments would need to be applied and monitored to ensure the water is consistently safe. While pesticides are currently the preferred mechanism for treating water, other technology such as UV light is in development and may be used in the future.

All pesticide products would be subject to EPA regulation under FIFRA. EPA-registered pesticide products are evaluated to determine potential environmental effects and potential impacts to human health specific to their use. Some of these products may be used to treat various types of irrigation water (e.g., may be used to treat the water drawn from lagoons or furrow pits to irrigate crops), or to treat the equipment used to irrigate crop-land.

FDA does not consider the misuse of pesticides to be reasonably foreseeable for various reasons related to farm operations. The misuse of pesticide by over application could potentially lead to crop losses, soil degradation, and other unforeseen effects, which in turn would further result in economic impacts to the farmer (Aktar et al., 2009; USDA NRCS, 2013a). Moreover, the EPA, which regulates water quality, issues guidance's for control of pesticides potentially entering the waters of the United States. The states' departments of environment or other water quality governing departments place further regulations on pesticide application for which pesticide applicators must receive a permit, certification or license. The person(s) applying the pesticides must follow these regulations, either after obtaining a license/certification or under the supervision of someone possessing these certifications. Therefore, due to potential fines or restrictions placed on the pesticide applicator, it is reasonably foreseeable that the application of pesticides with irrigation water will be done in accordance with federal and state guidelines, along with the individual pesticide label recommendations for application. Further, pesticides can be costly; therefore, it is unlikely that a farmer will purchase and apply more pesticide product than what is necessary to operate their farm.

FDA does not have specific information on the pesticides that would be submitted to EPA for registration for uses to control pathogens in irrigation water applied to produce. However, as described in greater detail in Chapter 3.1, the most commonly used antimicrobials are chlorine chemicals, specifically sodium hypochlorite, calcium hypochlorite, gaseous chlorine and chlorine dioxide. It is anticipated that chlorine compounds would be among the preferred chemicals for which industry would seek FIFRA registration. The primary byproduct of these chemicals is

[12] http://www2.epa.gov/pesticide-registration.

trihalomethanes, or THMs, which are commonly formed when the naturally occurring organics in water come in contact with reactive chlorine producing compounds. Under most conditions (except in the presence of unusually high bromide concentrations), chloroform is the THM produced in the highest concentrations during chlorination.

Chloroform is also one of the VOCs detected most frequently in both ground and surface water (Ivahnenko and Barbash, 2004). A national water quality assessment performed by the USGS was designed to provide additional information on the frequency of occurrence, concentration, and temporal variability of THMs in source water used by community water systems (CWS) (USGS, 2003b). This study found that THMs were detected in 47.8 percent of the CWSs supplied by surface water. Total THM concentrations of the compound, however, were typically less than the MCL and, therefore, would not be anticipated to result in significant adverse impacts. In the studies that compared land-use settings, frequencies of detection of chloroform were found to be higher beneath urban and residential areas than beneath agricultural or undeveloped areas (Ivahnenko and Barbash, 2004). As chlorine compounds are frequently used in municipal water systems, the presence of chloroform beneath urban and residential areas is unlikely to be tied to agricultural use.

USDA organic regulations, codified in 7 CFR Part 205, restrict chemical treatment products used under the National Organic Program to those that are listed on the National List of Allowed and Prohibited Substances (see Chapter 1.4). This limits the pool of available chemical treatment options for growers of covered produce that participate in the National Organic Program; however, EPA has approved some pesticides that fall into compliance for use under USDA organic regulations, under certain circumstances. Regulations specifying these circumstances are detailed under 7 CFR 205.601. In order for organic farmers to remain in the organic program, any EPA-registered pesticide that could be used to treat contaminated irrigation water would need to be an allowed substance on the National List, which adheres to strict environmental criteria.

Regions that would potentially require a higher level of chemical treatment of irrigation water because they already experience high exceedances of surface water quality criteria include regions A, B, C, L, R, T, and U (compare Figures 3.1-16 and 3.1-17 in Chapter 3.1.3.9 to Figure 1.7-4). To the extent there is a future registered pesticide use for treatment of irrigation water, it is theoretically possible it may include a chemical that results in the formation of THMs that could potentially have adverse human health impacts; however, such impacts may be avoided to the extent that covered farms choose other reasonably foreseeable management decisions, particularly switching water sources, switching the irrigation method to a non-contact method, or adding mechanisms to account for microbial die-off in the field and post-harvest (Alternative I and III only). Future approved uses of registered pesticides for treatment of irrigation water are speculative and unknown, and therefore we are not able to evaluate environmental impacts associated with possible future uses for purposes of this EIS. As discussed above, switching water source is a likely management decision, although the likelihood varies depending on the alternative. The adoption of this management decision is more likely for Alternative II than for Alternatives I or III, which provide for a mechanism to account for microbial die-off in the field and/or removal, post-harvest.

Switching water source

The public comments that FDA received following the publication of the 2013 proposed rule made it clear that the stringency of the requirements in Alternative II made a change in water source a viable option for covered farms.

Farmers in specific regions, such as the Pacific Northwest, indicated that drawing from groundwater may be the most feasible alternative for complying with the standard in Alternatives II and IV-b. Alternatives I, IV-a, III, and IV-c provide considerably more flexibility in meeting the water quality standard, including allowing for a microbial die-off and/or removal step(s). Reactions and verbal comments from some in industry and trade groups that FDA received on the supplemental proposed rule suggest that the proposed provisions for microbial die-off and/or removal to achieve the proposed microbial quality standard considerably limit the perceived need to change water source in order to comply with Alternative I (and similarly Alternatives IV-a, III, and IV-c), compared to Alternatives II and IV-b. FDA received no conflicting comments to the same topic during the Draft EIS public comment period. Alternatives IV-a, IV-b, and IV-c allow for the standards considered under Alternatives I, II, and III, respectively, to include root crops that are irrigated using low flow methods, where water is intended to, or likely to, contact the harvestable portion of the covered produce below the soil surface.[13]

By and large, groundwater sources are less contaminated than surface water sources (Chapter 3.1); therefore, it is likely that, if faced with contaminated irrigation water issues to the point where the water may not be treated at all or microbial die-off and/or removal options are not feasible, the grower may switch from surface water to groundwater irrigation. Groundwater depletion is primarily caused by sustained groundwater pumping. Pumping groundwater at a faster rate than it can be recharged can have adverse impacts on the environment.

The geographic distribution of total, surface water, and groundwater withdrawals for irrigation is shown in Chapter 3.1, Figure 3.1-13. Agriculture is a major user of ground and surface water in the United States, accounting for approximately 80 percent of the Nation's consumptive water use and over 90 percent in many Western states. Over the course of the past couple decades, groundwater has become an increasingly important source for irrigation and currently is used in 60 percent of the area equipped for irrigation within the United States (Siebert et al., 2010). The majority of withdrawals (85 percent) and irrigated acres (74 percent) have been in the 17 Western states where average annual precipitation typically is less than 20 inches and is insufficient to support crops without supplemental water. In 2005, approximately 20 percent (82,600 million gallons per day (Mgal/d)) of total national water withdrawals (about 410,000 Mgal/d) came from groundwater sources. More than one-half of the groundwater used for irrigation was withdrawn in just four states: California, Nebraska, Arkansas, and Texas. Irrigation represents the largest use of groundwater in 25 states. Nationwide, groundwater withdrawals for irrigation were approximately 3.5 times larger than groundwater withdrawals for public supply (USGS, 2009).

[13] Public testimony during the November 13, 2014 public meeting can be found: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm418878.htm.

Expansion of groundwater-fed irrigation is attributed to the ubiquity of groundwater, ready access to this resource, minimal infrastructure requirements, and general continuity of supply providing a buffer against droughts (Giordano, 2009).

Total irrigation withdrawals in both Eastern and Western states were smaller in 2005 than in 2000, but because the West accounts for such a large percentage of the total irrigation withdrawals, changes in those states have a greater effect on the total. Groundwater withdrawals increased slightly in the East, and surface-water withdrawals declined in both the East and West. During this period, total irrigated acres decreased in the West by 4 percent and increased in the East by 5 percent. In the West, acres irrigated by surface irrigation methods declined by 16 percent, and acres irrigated by sprinkler methods increased by 9 percent. Irrigated acres in the East increased for all types of systems; the largest percentage increase was in microirrigation systems.

In particular, California, Idaho, Texas, and Arizona (regions B, C, D, I and J) (see Chapter 3.1.3.8) are located in areas where the average annual precipitation typically is 20 to 30 inches, which is insufficient to support crops without supplemental water, and account for more than 80 percent of the covered produce grown in the United States. In addition, Region U is presently experiencing significant drawdown effects despite a much higher precipitation and aquifer recharge rate (see Chapter 3.1.3.11 and Chapter 4.1). Therefore, regions that may experience the highest potential impacts related to groundwater withdrawal include regions B, C, D, I, J, and U (and corresponding areas in which aquifers are shared across the border of regions D, I, and J with the northeastern and northcentral reaches of Mexico (see Chapters 3.1.3.7 and 3.1.3.11)). The most severe consequences of replacing surface water irrigation sources with groundwater are that excessive groundwater pumping can lead to lowering the water table, reduction of water in streams and lakes, deterioration of water quality, and land subsidence. These impacts may be disproportionately felt by Native American Tribes as groundwater drawdown could have potential environmental impacts including socioeconomic impacts related to access to water on reservations, particularly in regions B and J (see Figure 3.7-6).[14]

Lowering the water table

Droughts, seasonal variations in rainfall, and pumping affect underground water levels. If a well is pumped at a faster rate than an aquifer is recharged (by precipitation or other underground flow), water levels in the well can drop, resulting in decreased water availability and deterioration of groundwater quality. Lowering the groundwater table by only a few meters also affects existing users of groundwater, especially at dry times of the year. Springs are fed by groundwater and may dry up if the level falls. Similarly low flows in rivers may be reduced.

Groundwater pumping can alter how water moves between an aquifer and a stream, lake, or wetland by either intercepting groundwater flow that discharges into the surface-water body under natural conditions, or by increasing the rate of water movement from the surface-water body into an aquifer.

[14] Comparing the regions that experience the most significant effects of groundwater drawdown (regions B, C, D, I, J, and U) with the regions where Native American Indian reservations exist and where covered produce is grown (see Figure 3.7-6) shows that regions B and J are where Native American Indian reservations overlap with regions experiencing significant groundwater withdrawals.

Deterioration of water quality

The changing hydrological regime associated with irrigation schemes may alter the capacity of the environment to assimilate water soluble pollution. In particular, reductions in low flows result in increased pollutant concentrations already discharged into the water course either from point sources, such as industry, irrigation drains and urban areas, or from non-point sources, such as agrochemicals leaking into groundwater and soil erosion. Reduced flood flows may remove beneficial flushing, and reservoirs may cause further concentration of pollutants.

All of the water in the ground is not fresh water; much of the very deep groundwater and water below sea level can be saline. Under natural conditions the boundary between the freshwater and saltwater tends to be relatively stable, but groundwater pumping can cause saltwater to migrate inland and upward, resulting in saltwater contamination of the freshwater supply (saltwater intrusion).

Land subsidence

Land subsidence is a gradual settling or sudden sinking of the Earth's surface owing to subsurface movement of earth materials. Excessive groundwater pumping and aquifer depletion can cause land to sink, which can cause permanent loss of groundwater storage in the aquifer system and infrastructure damage (Todd, 1980). Vulnerable areas are those with compressible strata, such as clays and some fine-grained sediments. Any structural change in the soil is often irreversible. The ground level can fall with a lowering of the water table if the soils are organic rather than mineral based.

Regions that may be most impacted in terms of potential land subsidence, including any additive effects by farms switching to groundwater sources, include the regions that already experience the highest groundwater withdrawals; these are regions B, C, D, I, J, and U. Any action that may lead to increases in groundwater drawdown within the regions listed here would be considered a significant environmental impact.

Alternatively, as discussed in Chapter 3.3, and in terms of water conservation, drip irrigation and other low-flow irrigation methods conserve water effectively, but water infiltration rates vary by soil consistency. Furthermore, pathogen survival and transport from soil surface to the subsurface root zone varies by soil type and the size of pore spaces, but consistent studies have not been performed nationwide on these processes, and little is actually known about potential impacts. As discussed earlier in this subpart, although low-flow irrigation does increase the potential that uncultivated fields are placed into cultivation thereby increasing water use, the more likely scenario is that drought conditions have already forced some farmers to convert much of their irrigation to low-flow. Overall, because improved water conservation technology such as how drip and low-flow technologies perform is not directly expected to result in conditions where water sources/resources are unable to recover to ambient conditions, and because some farms may already have converted to these water conservation technologies (potentially in response to drought conditions in certain areas of the U.S.), FDA anticipates that there are minimal impacts associated with drip and low-flow irrigation as it relates to water resources.

Switching the irrigation method to a non-contact method
Non-contact irrigation can include certain types of surface irrigation (e.g., furrow) and sub-irrigation methods (e.g., indus basin irrigation system (IBIS)). Each of these systems is discussed in more detail in Appendix B.

Non-contact irrigation methods include systems that deliver water directly to the root zone of the crop at or below the soil surface, and where the agricultural water is intended to, or likely to, contact the harvestable or harvested portion of root crops (see Appendix B). Such use of agricultural water is covered under the PS PR. However, some subsurface and drip irrigation systems used only for the root zone and where the roots are not harvestable or harvested is not covered under the agricultural water requirements of the PS PR.

Changes in irrigation method to the use of non-contact methods is a management decision that is only feasible for specific crops. For crops such as apples where direct application of water can prevent brown spots, switching to non-contact methods is not feasible.

Non-contact irrigation allows efficient watering by supplying water where it is needed, at or near the roots of the plants. This approach significantly reduces water percolation through the root zone which in turn leads to decreased runoff from the tail end of gravity irrigated fields, and lower evaporation from the soil; even more advanced flood irrigation systems may be controlled with a system of dikes and levees in extreme flood situations. However, smaller systems are notable exceptions and may contribute to excess runoff. Flood irrigation methods are also often associated with poorer water quality conditions in the tailwater (see discussion in Appendix B).

Overall, most non-contact irrigation provides greater uniformity in the water distribution throughout a field leading to a reduction of moisture stress to plants. Non-contact irrigation also generally allows the precise application of water-carried fertilizers to the roots of the plant, which can considerably increase irrigation efficiency and thereby reduce migration of these chemicals and pesticides into the aquifer. This benefit has been reported by many researchers (Allen, 1993). Furthermore, if irrigation water could be applied to exactly meet the evapotranspiration needs of the crop, then it is apparent that less water, and therefore less salts, would be applied. Without excess water and deep percolation, fertilizers and agricultural chemicals would not likely be washed down into the aquifer, and groundwater quality would improve.

A conversion to more efficient irrigation technology (e.g., switching from an overhead irrigation method to low-flow methods such as drip irrigation—see discussion at Chapter 3.3.3.5) can induce a shift away from dry-land crops to irrigated crops, from less water-intensive crops to more water-intensive crops, or from drought-resistant varieties to varieties that require consistent rates of irrigation. Even if the producer does not switch crops, the higher yields made possible through more efficient irrigation technology cause higher rates of evapotranspiration, resulting in less irrigation water being returned to the watershed either as recharge to the aquifer or return flow to surface water sources. For example, in Kansas and other places where the rights system defines an annual limit to the amount of irrigation water that can be used by a producer, water "saved" through increased irrigation efficiency may be used on previously unirrigated land, thus increasing total irrigated acreage (Scheierling, 2004).

Although non-contact irrigation does increase the potential that uncultivated fields are placed into cultivation, thereby increasing water use, the more likely scenario is that drought conditions have already forced farmers to convert much of their irrigation to non-contact, and any anticipated water-related impacts are not anticipated to be significant because the conditions that may cause such a management decision are persistent.

Add mechanism to account for microbial die-off in the field and post-harvest
A management decision to account for microbial die-off and/or removal post-harvest is only possible for Alternatives I, IV-a, III, and IV-c.[15] Microbial die-off and removal can be reasonably expected due to natural die-off on the field post irrigation and prior to harvesting of the crop; microbial die-off or removal can occur under certain conditions and/or during extended storage or commercial washing of the produce commodity. Post-harvest steps may also involve the use of some industry-specific antimicrobial direct or indirect food additives or pesticides that are applied as mechanisms to improve microbial die-off post-harvest. Such treatments may also reduce reliance on chemical treatments of contaminated irrigation water supplies or may augment treatments depending upon the overall quality of the water (i.e., the worse the water quality, the more treatment options that may need to be employed pre- and post-harvest).

Since water resources are already stressed over the majority of areas that may be most affected by the PS PR (regions B, C, D, I, J, and U), it is likely that the water application rates have already been largely balanced with the required plant uptake, and although the application rates and durations may change the total volume of water applied to crops, it is likely to remain fairly constant. Therefore, post-harvest treatment is a viable management decision option that may reduce the potential for significant environmental impacts associated with other management decisions reviewed under this alternative.

Among the responsibilities of the FDA is regulation of components of food contact substances. Once known as indirect food additives, FDA now refers to these materials as food contact substances (FCS). An FCS is "any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food" (21 CFR 170.3(e)(3)). Common types of food contact substances include coatings, plastics, paper, adhesives, as well as colorants, antimicrobials, and antioxidants found in packaging. In an effort to ensure the safe use of these substances, FDA has established a Food Contact Notification (FCN) Program within the Center for Food Safety and Applied Nutrition's (CFSAN) Office of Food Additive Safety. All phases of the product review and approval process for products that undergo review by the FCN Program are described at FDA's Web page.[16] FCNs are agency actions of a type requiring environmental consideration. After an FCN becomes effective, the agency adds it to the environmental inventory of effective notifications on the internet in compliance with NEPA requirements for public involvement. An inventory of environmental impact decisions, including

[15] As discussed in Chapter 2.1, subpart E discusses the three subalternatives that are included under Alternative IV. Alternative IV-a applies the standard as proposed under Alternative I (proposed § 112.44(c)), however, Alternative IV-a also applies the standard to root crops. Alternative IV-b applies to root crops and Alternative II. Alternative IV-c applies to root crops and Alternative III.
[16] http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/ucm064161.htm.

for antimicrobial products, is found on the agency's Web site.[17] To date, FDA has not identified any significant impacts related to the use of indirect additives or FCS that would require the preparation of an EIS.

Post-harvest microbial die-off and/or removal mechanisms do not necessarily mean taking active methods to wash the produce. Allowing for a sufficient interval post application of agricultural water may be sufficient in many situations. Therefore, while post-harvest washes are one option, they are not expected to add significant pressures to local water supplies. Further, as the impact of the available FCSs have already been reviewed and found not to result in significant adverse impacts, they are not anticipated to considerably contribute to the degradation of water effluent that may be dispensed to a municipal water collection system or to an individual septic system. Therefore, there are no anticipated adverse impacts to water quality as a result of the post-harvest treatment with microbial removal washes for produce.

Stop Growing Covered Produce

Based on the comments FDA received on the supplemental proposed rule, the decision to stop growing covered produce is not a preferred management decision except in limited instances. Whether farmers stop growing covered produce is dependent upon the alternative use of the land. In California, severe drought conditions have already forced many farmers to let land lay fallow (California Farm Water Coalition (CFWC), 2014; Howitt et al., 2014). It is widely reported that a shortage of water resources has prompted programs in California that pay farmers to keep land fallow in order to divert water to the cities. This is not a re-zoning of the land *per se*; rather, that land is essentially reserved for future alternative agricultural uses. In other areas of the country where water is more abundant, land formerly used to grow covered produce may be employed to raise livestock or other crops, although this is not commonly practiced and would require intense capital costs to accomplish.

Therefore, if covered produce is no longer grown and the land is to remain fallow, it most likely would be due to the scarcity of water, and the overall water use would remain similar since the water would be diverted to other uses.

If non-covered produce or other agricultural crops that are not produce are grown,[18] regulation or requirements to maintain certain water quality conditions would be dependent on any existing state regulations or industry marketing agreements, or may not be addressed because potential forms of contamination may be addressed through commercial processing. The type of crop a farmer may select to grow would also be dependent upon the region's climate, soils, and water availability, and may involve a decision whether the existing farm's equipment and infrastructure would be sufficient, or would need to be updated, modified, or bought to accommodate a new type of crop.

Under certain conditions, where very small farms are involved and costs may be a larger factor, some farms may decide to stop growing crops altogether. However, this scenario would be most

[17] http://www.accessdata.fda.gov/scripts/fdcc/?set=ENV-FCN.

[18] See Chapter 1.6. Produce that are not covered under the PS PR are identified as specific fruits and vegetables that would be exempt from the rule (Table 1.6-1), or produce that is specifically meant for commercial processing using a method that adequately reduces the presence of microorganisms of public health significance.

likely for very small farms as well as livestock operations that grow small amounts of covered produce; many such diversified farming-livestock operations would likely be excluded based on the proposed monetary threshold for excluded farms applied to sales of produce only rather than sales of food.

Any potential impacts on water resources are dependent upon the alternative use of the land. In some cases severe drought conditions have already forced many farmers to let land lay fallow. Under most conditions, a change in the type of agricultural use may not substantially change the water being used for the purposes of farming. Letting a parcel of land go fallow would reduce the pressure on water supply and eliminate water quality regulatory conditions, but that land may remain fallow until a time when it is needed again or may transfer to another type of use. Any land management changes are highly speculative and would occur based on local management decisions and personal economic considerations. Overall, there is a low probability that water resources would result in any significant adverse effects under this action.

Biological and Ecological Resources- Biological and ecological resources require water to be available for their sustainability. Water is a life requisite and any change in the quantity or quality of available water may pose a threat to biological and ecological resources. Once water is used for agricultural purposes, a portion of that water may re-enter the groundwater and surface water ecosystems. The quantity, quality, and fate of the used agricultural water may be altered from current conditions to a level that changes the interactions of biological and ecological resources with available water supplies. No significant adverse impacts on biological and ecological resources are identified with the decisions to switch the irrigation method to a non-contact method, cease growing covered produce, or practice measures that could allow for microbial die-off. These management decisions may, in select instances, result in beneficial impacts by allowing land to lay fallow, or reducing runoff of nitrogen compounds or other agricultural-related contaminants. The only management decisions that have the potential for adverse impacts on biological and ecological resources would be the use of chemical treatment to bring agricultural water sources into compliance with any of the alternatives' water requirements or switching water sources.

Any potential acute toxicity-related impacts would be product-specific. There is no EPA-registered pesticide that is approved for use for antimicrobial treatment of irrigation water used during the growing of crops. Therefore, we are not able to evaluate the environmental impacts to biological and ecological resources from an unapproved and unknown use. However, generally, we would anticipate that any such impacts would not be significant providing that any product that is used is handled and disposed of in accordance with labeling requirements; as explained earlier in this chapter, handling and disposing of such products in accordance with labeling requirements is the reasonably foreseeable use (see subheading for Water Resources under the management decision, *Use of Chemical Treatment to Bring Agricultural Water Sources into Compliance).*

FDA received public comment on the Draft EIS regarding the impacts of chemical treatments (application of pesticides) to biological and ecological resources. FDA has considered these comments and added supporting documentation in Chapter 3.1.3.10 regarding pesticide persistence and mobility. The discussion in the next subsection regarding *Use of Chemical Treatment to Bring Agricultural Water Sources into Compliance* contains information on pesticide

handling and EPA's pesticide registration process, which is, in part, based on ecological risk assessments conducted by that agency.

Use of Chemical Treatment to Bring Agricultural Water Sources into Compliance
Chemicals such as pesticides used for the treatment of agricultural water are not natural to the ecosystem, may be acutely hazardous, and are required to be disposed of properly (EPA, 2014l). The persistence of these chemicals in the environment may adversely influence non-target systems (e.g., wetlands and riparian ecology) and have further indirect effects to flora and fauna coming into contact with those chemicals, increasing toxicity.

EPA's online Pesticide Registration Manual specifically states, "Pesticides are substances that prevent, destroy, repel, or mitigate a pest. A product's relative toxicity to humans or other non-target organisms does not make it a pesticide. However, the product's toxicity to humans and other organisms is carefully evaluated during EPA's registration evaluation process. When EPA determines that a pesticide product can be registered for use, the Agency has concluded that the use of the pesticide product will not cause unreasonable adverse effects to humans or the environment when applied according to the label directions and restrictions (EPA, 2014m).[19]

Therefore, we would anticipate that any pesticide that is EPA-registered and is handled and applied in accordance with labeling requirements—which would be a reasonably foreseeable use of such products—to not result in significant environmental impacts to vegetation, wildlife, and wetland resources. Theoretically, an application of an antimicrobial chemical may result in short-term minimal to moderate impacts on these resources particularly if applied preceding substantial periods of precipitation which may increase runoff. Such impacts would be intermittent and acute and at this time unknown because there are no EPA registered pesticides for use for antimicrobial treatment of agricultural water used during the growing of crops.

Switching water source
Habitats both within and alongside rivers are particularly rich, often supporting a high diversity of species. Changing the source of irrigation water is not anticipated to directly affect the biological and ecological resources of the nation; however, large-scale regional depletion of groundwater resources, if unable to recover to ambient conditions through normal seasonal and/or annual water cycles, may significantly impact wetlands, lakes, and streams and the species that rely on them. Loss of groundwater storage in some cases may drain wetlands and surface waters to the extent that local wildlife populations may not be sustained at their present levels (loss of forage, cover, and breeding opportunities) and may lower groundwater levels below the depth that streamside or wetland vegetation needs to survive. The overall effect would be a loss of riparian vegetation and wildlife habitat. However, such impacts may be more likely in regions that experience substantial pressure on the aquifer system, such as regions B, C, D, I, J, and U, and the northeastern and northcentral areas of Mexico that correspond to aquifers located within regions D, I, and J, as compared to other regions identified in this EIS. It should be noted that regions B, C, D, I, J, and U are regions in which more than 80 percent of covered produce is grown in the United States, and that a high percentage of the growers in these regions already participate in State or industry

[19] http://www2.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide#toxicity.

marketing agreements, some of which (e.g., CA and AZ LGMA, T-GAPs) already meet numeric agricultural water quality standards that are the same as, or more stringent than, what FDA proposes (see Table 2.1-1 in Chapter 2).

The ecology of estuaries is sensitive to the salinity of the water, which may be determined by low stream flows. Saline intrusion into the estuary would also affect fish catches. Saltwater intrusion into freshwater coastal rivers and aquifers is a challenge for water resource managers, and a reduction in water flow caused by water withdrawals (surface and groundwater) can accelerate the landward movement of the freshwater-saltwater interface (see Chapters 3.3.1.6 and 3.3.1.11). Increases in water withdrawals can result in saltwater intrusion, which then may result in significant impacts to aquatic plants and wildlife.

Vegetation and Wildlife

The natural vegetation and terrestrial, avian and aquatic wildlife that can be found in any region varies. While the exact vegetative and wildlife make-up depend on a variety of factors, water plays a key role. With respect to the organisms located on or near covered farms, stream corridors adjacent to these and other farm operations help to support the natural vegetation which provides habitat and food for wildlife. Agricultural practices such as irrigation consume water from either surface or groundwater sources, which may limit the availability of water for vegetation and wildlife resources adjacent to or downstream of the farm operation. As described in Chapter 3.1.3.5, there are interactions between surface and groundwater. Changes in water source used by farms may result in unintended impacts on water availability, which organisms rely upon.

A standard directed to agricultural water quality may also increase the need for impaired waters to be treated in order to be brought into compliance with the standard. This has the potential to increase the chemical contamination of nearby waterways, and potentially to impact local vegetation.

Wetlands

Wetlands, by definition, require water to support hydrophytic vegetation, hydrology, and hydric soils. Changes in water quality and availability have the potential to influence wetland functions and values. Specifically, water withdrawals from agricultural practices may influence water availability and, thus, influence wetland function and value (as a habitat). Generally, wetlands filter contaminants and nutrients from water sources, a process that has the potential to improve water quality conditions downstream of the wetland.

Soils- Standards directed to agricultural water are not intended to have direct effects on soils. However, as described in Chapter 3.3.3.4, the USGS has identified that more than 80 percent of the identified subsidence in the nation is a consequence of groundwater exploitation. In many areas of arid western regions and in more humid areas underlain by soluble rocks such as limestone, gypsum, or salt, land subsidence is an often overlooked environmental consequence of land- and water-use practices. Figures 3.1-23 and 3.1-24 in Chapter 3.1 show the extent of excessive groundwater pumpage of aquifer systems throughout the U.S. which correlate to areas where land subsidence is most likely to occur. Actions that will increase reliance on groundwater will potentially also impact soils. As soil can regulate the drainage, flow and storage of water and solutes, which includes nitrogen, phosphorus, pesticides, and other nutrients and compounds

dissolved in the water, and as described in Chapter 3.3.3.5, soil plays a role in the removal of pathogens. An impact on soils resulting from groundwater drawdown may result in impacts that are in addition to, but related to, irreversible compaction or subsidence, such as reduced ability to partition water for groundwater recharge and for use by plants and soil organisms. Such impacts are considered to be significant.

Regions where groundwater withdrawal may have the highest influence on land subsidence, and thus permanent damage to soils, are B, C, D, I, J, and U, and the northeastern and northcentral areas of Mexico that correspond to aquifers located within regions D, I, and J. As discussed above under water resources, these regions all correspond to covered produce growing regions in the U.S. Therefore, impacts on groundwater resources, where steps are not taken to minimize the impacts as discussed in Chapter 3.1.3.11, may result in irreversible impacts on soils and corresponding impacts on the ability of those soils to filter nutrients, chemicals and pathogens.

We have identified no significant adverse impacts on biological and ecological resources with the decisions to switch the irrigation method to a non-contact method, to cease growing covered produce, and to practice measures that could allow for die-off. Changes in irrigation methods would result in beneficial impacts due to improved moisture retainment due to lower soil water evaporation rates, and may also improve overall soil quality by reducing the erosive effects of wind and rain and allowing organic material in soils to remain.

Use of Chemical Treatment to Bring Agricultural Water Sources into Compliance
As presented in Chapter 3.3.3.5, chloride is not adsorbed by soils and moves readily with the soil-water, is taken up by the crop, moves in the transpiration stream, and accumulates in the leaves. The chemical reactions that occur when chlorine and organic matter are exposed to each other also produce toxic and carcinogenic by-products. The use of antimicrobials, however, would not be expected to exceed the threshold that would be toxic to crops, as long as labeling requirements are followed for application purposes, and adverse effects to crops from overexposure to chemical treatments should not occur.

Switching water source
As discussed previously, FDA received public comment to the proposed rule asserting that covered farms consider it more feasible to switch water sources under Alternative II than under Alternatives I or III. Soil types influence the selection of irrigation methods and irrigation schemes. Many farms use a sprinkler or drip irrigation scheme when the land contains a variety of soil types. The effect of switching from surface sprinkler irrigation to surface furrow irrigation can negatively affect soil structural properties due to over wetting and nutrient availability due to wetting pattern concentrating nutrients in a limited area. A change in water source from surface to groundwater could negatively impact soils by the effects of aquifer consolidation on soil structure. Regions that may experience adverse impacts to soil structure through land subsidence, which is not reversible, and where impacts would be most pronounced if Alternative II or IV-b were finalized, include regions B, C, D, I, J, and U, and the northeastern and northcentral areas of Mexico that correspond to aquifers located within regions D, I, and J, as discussed earlier in this section.

Waste Generation, Disposal, and Resource Use- Standards directed at agricultural water would not result in waste generation or resource use beyond those described above for water. As such, there would be no impacts in this resource component for any alternative.

Air Quality and Greenhouse Gases- Standards directed at agricultural water would primarily be expected to impact air quality and greenhouse gas (GHG) emissions if the management decisions result in an increase in energy use (because of the burning of fossil fuels) in order to operate irrigation equipment (e.g., groundwater pumps) and other agricultural equipment associated with post-harvest operations (wash and cooling water). As discussed in Chapter 3.5.3, in 2008, approximately 49 million acres of U.S. farmland were irrigated with pumps powered by liquid fuels, natural gas, and electricity (USDA CCPO, 2011). Electricity was the main power source for these pumps, costing $1.5 billion to irrigate about 30 million acres. Diesel fuel was used to power pumps on about 13 million acres and natural gas was used on about 4.7 million acres (USDA NASS, 2009e).

Although electricity generation is often analyzed as a major source of GHG emissions, electricity is ultimately consumed in different economic sectors. Electricity-related GHG emissions are mostly distributed among the industrial, transportation, commercial, and residential economic sectors. According to the EPA, in 2012, electricity-related emissions were responsible for approximately 62.2 Tg CO_2 Eq. of the 676.3 Tg CO_2 Eq. total GHG emissions from all uses in the agricultural sector. This represents only three percent of the total GHG emissions attributed to the electric power industry in 2012 (EPA, 2014k).

As discussed in Chapter 3.5.3, the primary non-attainment areas for NAAQS in areas where covered produce are prevalent are due to non-attainment for PM_{10}, $PM_{2.5}$ (based on EPA Green Book data) and ozone (based on the current 2008 standard and the maintenance areas associated with the older 1997 standard). These regions are illustrated in Figure 3.5-3, 3.5-4, and 3.5-6 respectively (EPA, 2014i). The highest concentrations of particulate matter and ozone non-attainment areas that overlap with covered produce operations occur in central and southern California (regions C and D).

Standards directed at agricultural water are not expected to result in significant environmental impacts regardless of the management decision that is chosen. Some management decisions may result in minimal impacts as discussed below, but none is expected to be significant because such decisions would not be expected to occur in areas where the contributions along with other emissions would contribute to increases in criteria pollutants and/or increase GHG emissions that may result in considerable public health concerns at a regional or national level.

Use of Chemical Treatment to Bring Agricultural Water Sources into Compliance
Applying a chemical treatment to contaminated agricultural waters is not anticipated to impact air quality and greenhouse gases on a regional or national scale, as there would be no foreseeable measureable change to the air quality environment by adopting this mechanism to comply with the standard.

There is the potential for an increase in localized vehicles-miles-traveled for hauling chemicals to farms. Certain regions in the U.S. that include non-attainment or maintenance areas (e.g.,

California) would be sensitive to these potential localized impacts on criteria air pollutants (NAAQS), and other federal or state regulations on hazardous air pollutants would apply.

Substances that may be used in crop production, such as calcium hypochlorite, sodium hypochlorite, and chlorine dioxide, are all synthetic materials not found in nature. Neither calcium hypochlorite nor sodium hypochlorite is persistent in the environment. When released to air, these substances are broken down by sunlight to compounds commonly found in the air. Chlorine dioxide is not persistent in the environment. Chlorine dioxide is a very reactive and breaks down quickly. In air, sunlight rapidly causes chlorine dioxide to break down into chlorine gas and oxygen (USDA AMS, 2011). In water and soil, sodium and calcium hypochlorite separate into sodium, calcium, hypochlorite ions, and hypochlorous acid molecules. Calcium hypochlorite and sodium hypochlorite are not bioaccumulative (USDA AMS, 2011).

Switching the irrigation method to a non-contact method
Switching irrigation methods to non-contact systems can lead to differences in CO_2 and criteria pollutants depending upon the energy source requirement for the irrigation method, although the direction of change may vary depending on the changes in energy use and management practices involved. Any anticipated impacts would be speculative, but even if they occur, FDA does not consider these impacts would be significant, especially if the management decision results in switching from a sprinkler method where water is broadcast widely to a less energy intensive method.

Switching water source
Changing the normal irrigation method due to contaminated agricultural waters is not anticipated to impact air quality and greenhouse gases on a national scale, as there would be no foreseeable measureable change to the air quality environment by adopting this mechanism to comply with the standard. Based on 2007/2008 statistics, FDA estimates that 18.36 percent (7,440) of affected produce farms use irrigation. We also estimate that slightly less than half of those produce farms apply irrigation water during the growing season (FDA, 2013b).

There may be increases in CO_2 emissions if there were a potential increase in energy use from pumping by switching the form of irrigation. There could also be a decrease in energy use from switching from a spray/contact irrigation method to a non-contact method where the system is fed by gravity rather than pumping or where there is less demand for energy through electricity or alternative fuels. In other words, the possible increases and decreases of energy use depending upon the mechanism used to irrigate a crop may result in a net balance of energy use in any given region. Finally, changing the irrigation method could lead to reductions in particulate matter emissions due to less soil disturbance, or may increase dust-related particulate matter due to potentially drier soil surfaces. Since energy use (and corresponding GHGs) and dust-related particulates may be balanced and, therefore, are not expected to substantially alter existing conditions, FDA does not consider these impacts to be significant.

Socioeconomics and Environmental Justice- The loss of employment or income that is associated with meeting the requirements for standards directed to agricultural water could stem from economic costs to comply with the standards. Such decisions could include changing irrigation methods, water source, testing of samples and/or the treatment of water to bring it in to compliance

with the rule. Treatment costs would be dependent on the chemical treatment technology chosen, the level at which the water source is contaminated, the amount of time the treatment would need to take place, and the type of water source being treated. These variables change the cost for each farm that may be potentially affected. In addition, management decisions could lead to environmental impacts resulting from changes in types of crops planted or changes in land use that may have socioeconomic impacts in the community (employment, shifts in the population). FDA has proposed and plans to finalize a rule with multiple provisions aimed at addressing a variety of potential routes of contamination of produce for human consumption. Socioeconomic and environmental justice issues will be addressed in the aggregate (with respect to provisions of the rule) under Chapter 4.7.

Environmental Justice –
In addition to the aggregate discussion in Chapter 4.7, we note that standards directed at agricultural water, if a pesticide is registered in the future to treat agricultural water used during the growing of crops, have the potential to adversely impact a) minority or low income groups if populations are situated in areas that see increases in secondary routes of exposure to pesticides or other chemicals used to bring water into compliance at concentrations that are sufficient to result in adverse health impacts; or b) minority or low income principal operators or farm workers if there is an increase in pesticide use for which they are responsible. However, as discussed in Chapter 4.1 under the subheading Human Health and Safety, there is no EPA-registered pesticide that is approved for use for antimicrobial treatment of irrigation water used during the growing of crops. As long as pesticides and other chemicals are applied in accordance with their labeling requirements, which would be a reasonably foreseeable use, FDA would not expect a significant impact on human health as a result of secondary or worker exposure to pesticides. Similarly, we would not anticipate significant impacts on minority primary operators or minority farm workers.

Human Health and Safety- As discussed earlier, agricultural water is a potential source of pathogen contamination for produce. Standards directed at agricultural water are intended to establish "science-based minimum standards directed to agricultural water that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the Food Drug and Cosmetic (FD&C) Act" (78 Fed. Reg. 3504). Any standard established under this statutory mandate would be expected to have significant beneficial impacts on human health.

In addition to the intended beneficial impacts on human health, there is the potential for adverse impacts on human health related to worker safety, secondary routes of exposure to pesticides, air quality effects which may arise from chemical treatment, changing the irrigation method to non-contact method, changing the water source, and ceasing to grow covered produce.

No adverse impacts on human health would be expected as a result of the decisions to switch the irrigation method to a non-contact method, switch water source, or use post-harvest mechanisms to allow for die-off and/or removal. Some minimal adverse impacts may be associated with the use of chemical treatment to bring agricultural water sources into compliance with any of the alternatives' water requirements, or a switch to producing agricultural commodities that are not

covered by the rule (cease growing covered produce). However, all management decisions would be expected to result in significant beneficial impacts on human health based on a reduction in the exposure to potential pathogens. FDA estimated that 240,347 foodborne illnesses attributable to growing/harvest (g/h) agricultural water and 281,736 foodborne illnesses attributable to postharvest (ph) agricultural water would be prevented through finalizing the requirements of the provisions as proposed in the 2013 proposed rule. This equates to an estimated 19.31 percent reduction in the risk of foodborne illness attributable to covered produce (FDA, 2014b).

Use of Chemical Treatment to Bring Agricultural Water Sources into Compliance

Chemical treatment of contaminated agricultural water and its associated health benefits (in reduced illnesses) may be tempered by the potential health-related impacts from chemical contamination of produce, soil, and surface water resources (presenting so-called secondary routes of exposure). The chemical treatment of agricultural water to achieve the water quality standard would reduce the potential pathogenic contamination of produce. FDA does not expect the use of approved products in accordance with labeling requirements to pose a significant human health risk because generally, human health risks are associated with the improper use of chemicals, which is not a reasonably foreseeable use of such products (see Chapter 4.1 under the subheading for Human Health and Safety). Human health risks are further minimized when using proper handling techniques including using recommended personal protective equipment (e.g., chemically resistant gloves to avoid exposures) as described by the manufacturer.

As discussed in Chapter 4.1, FDA does not have specific information on the pesticides that would be submitted to EPA for registration for uses to control pathogens in agricultural water applied to produce. However, as described in greater detail in Chapter 3.1, the most commonly used antimicrobials are chlorine chemicals: specifically sodium hypochlorite, calcium hypochlorite, gaseous chlorine and chlorine dioxide. We anticipate that chlorine compounds would be among the preferred chemicals for which industry would seek FIFRA registration. Using chlorinated products for chemical treatment could produce unsafe byproducts in the form of THMs when the chlorine comes into contact with organic compounds. As discussed in Chapter 3.1.3.10, Ivahnenko and Barbash (2004) found in studies that compared land-use settings, frequencies of detection of chloroform were higher beneath urban and residential areas than beneath agricultural or undeveloped areas due to the extent that municipal water is treated.

Regions that would potentially require a higher level of chemical treatment because they already experience high exceedances of surface water quality standards include regions A, B, C, L, R, T, and U (compare Figures 3.1-16 and 3.1-17 in Chapter 3.1.3.9 to Figure 1.7-4). To the extend there is a future registered pesticide use for treatment of agricultural water, it is theoretically possible it may include a chemical that results in the formation of THMs that could potentially have adverse human health impacts; however, such impacts may be avoided to the extent that covered farms choose other reasonably foreseeable management decisions, particularly switching water sources, switching the irrigation method to a non-contact method, or adding mechanisms to account for microbial die-off in the field and post-harvest.

Because the treatment of contaminated agricultural water, if an EPA-registered pesticide is approved for such use in the future, would satisfy the water quality requirement, there would be an anticipated beneficial impact associated with the minimization of foodborne illnesses. There

would be a risk to certain consumers from exposure to pesticides in their drinking water. However, we are not able to evaluate the environmental impact of that scenario in this EIS because there is no approved pesticide use and it would be speculative to do so. Any such risk may be minimized through regular monitoring of the water source and taking action (e.g., remediation, switching water source, using bottled water) if pesticides are found to be present in the water source due to treatment under the PS PR, if finalized (see Chapter 4.1 under the subheading for Human Health and Safety).

Cease growing covered produce
Potential consequences if growers were to switch to non-covered crops (i.e., non-covered produce or agricultural crops that are not produce) or let certain land lay fallow may include growers switching to non-covered crops that require different management practices such as the addition of fertilizer and pesticides, or crops that would be commercially processed. If new crops require additional inputs, water and soils could be adversely impacted. However, if growers were to switch crops to avoid complying with the final rule, they would likely select a crop that would require similar management practices to what they presently employ, in order to reduce the capital costs associated with the switch. However, we would anticipate that only a small number of growers (presently unquantifiable) operating near the margin between very small farms and excluded farms may make such a management decision to cease growing covered produce altogether.

Conclusions – Ultimately, the finalized standard, in conjunction with the existing water source, local water source availability, and water quality will play a role in influencing the management decisions that are chosen. More stringent numeric standards and those that do not allow for microbial die-off to be accounted for will increase the likelihood of chemical or other treatment of the water or permanent or semi-permanent changes in water source or irrigation method. No management decision is expected to be absolute. Farmers across the nation are expected to select their preferred management decision based on their unique conditions. The ability for farmers in different regions to select different management decisions will ultimately play a role in minimizing the overall environmental impacts of the rule. The anticipated impacts for each alternative are described and compared below under Alternatives Analysis.

4.2.1 Alternatives Analysis

This section provides a comparison of alternatives that FDA considered under Subpart E, and relates the potential environmental impacts from a grower that may select a particular management decision, as discussed at the beginning of this section.

Alternative I.
As Proposed. GM ≤ 126 CFU generic *E. coli*/100 ml and STV ≤ 410 CFU/100 ml
This alternative includes adding a mechanism(s) to account for microbial die-off and/or removal, so incorporating practices or measures that result in microbial die-off and/or removal is expected to be the preferred management decision.

Beneficial impacts are anticipated to human health as a result of reducing the potential for pathogens to contaminate produce and cause foodborne illness.

If a pesticide was registered and approved by EPA for use as an irrigation water treatment and a grower were to choose to use this chemical treatment to bring water into compliance, sustained, long-term water treatment may not be required because the added flexibility to account for die-off and/or removal is anticipated to result in few, intermittent impacts that are not significant because these steps may be as simple as allowing sufficient time between final application of agricultural water in the field and harvest, which are not expected to result in significant increases in demand for water or other resources.

As discussed under water resources above, disinfectants may be useful for reducing hazards that may cause foodborne illnesses; however, many of these disinfectants may form harmful byproducts. EPA-registered pesticide products are evaluated to determine potential environmental effects and potential impacts to human health specific to their use. Disinfection byproducts are a well-recognized hazard that would be considered as part of the analysis. Therefore, as long as the pesticides are handled and applied according to label directions, which would be a reasonably foreseeable use, no significant adverse impacts would result.

Adverse effects related to the use of chemical treatments, such as pesticides, may be limited because a high number of growers in key growing regions, such as California, Arizona, and Florida, participate in marketing agreements that have more stringent water quality standards than what FDA has proposed and are already using water that would be in compliance with the proposed standard.

Under this alternative, switching water source and ceasing to grow covered produce are not expected to be preferred management decisions. As discussed under the No Action Alternative, there are current and on-going significant adverse, long-term impacts resulting from the lowering of the water table, deteriorating water quality, and land subsidence—with each resulting from further groundwater withdrawals—and such switches to groundwater are already occurring and causing significant adverse impacts that would be independent of the proposed water standard. Any action that may lead to increases in groundwater drawdown would be considered a significant environmental impact. Regions that may be most impacted in terms of potential land subsidence, including any additive effects by switching to groundwater sources, include the regions that already experience the highest groundwater withdrawals; these are regions B, C, D, I, J, and U. Additionally, some impacts related to groundwater withdrawals may be felt in the northeastern and northcentral reaches of Mexico where these areas correspond to aquifers located in regions D, I, and J in the United States. Due to the added flexibility to account for microbial die-off in the field under Alternative I, coupled with the knowledge that a high amount of potentially affected growers participate in marketing agreements with more stringent numeric water quality standards than what FDA proposes, any potential effects related to Alternative I are not expected to contribute to the current adverse conditions to the extent that would occur under Alternatives II, III, IV-b, or IV-c.

Alternative II.
A single sample maximum of 235 CFU (or MPN) generic *E. coli* /100 ml single sample or a GM of no more than 126 CFU (or MPN)/100 ml

Under this alternative, switching water source is expected to be the preferred management decision. As compared to Alternative I, this alternative would not have the added flexibility to account for microbial die-off and/or removal; therefore, farmers are more likely to decide to switch water sources, particularly away from surface waters to a cleaner source. If the cleanest available source is groundwater, existing significant adverse conditions (i.e., water drawdown, potential subsidence, and the related continued degradation of water quality) may continue to be exacerbated but to a greater degree than Alternative I, because the water quality requirements would be more stringent under this alternative and more farms are potentially likely to switch to the groundwater source in numbers that may considerably influence groundwater sources. These impacts are expected to be limited to localized regions and are not expected to be widespread. The regions that may be most affected are B, C, D, I, J, and U (as previously identified at the beginning of this section and in Chapter 4.1), as well as corresponding areas in northeastern and northcentral reaches of Mexico that share an aquifer with regions D, I, and J in the United States. These regions may also experience irreversible effects to soils. Therefore, these impacts under Alternative II related to lowering the water table, deteriorating water quality, and land subsidence are considered significant adverse. Native American Tribes may be disproportionately impacted as groundwater drawdown could have potential environmental impacts including socioeconomic impacts related to access to water on reservations, particularly in regions B and J. Such impacts would be considered significant adverse.

Capital costs related to any switch in water source may be especially burdensome for very small businesses, which could potentially lead to additional impacts (e.g., potential loss of employment or income).

Treating any water source to remove harmful pathogens would have an added public health benefit by reducing the potential for foodborne illnesses.

Compared to Alternative I, the likelihood of a grower selecting a new water source may be higher due to the lack of added flexibility to account for microbial die-off and/or removal.

There would also be greater potential for the use of chemical treatments to bring water into compliance under this alternative relative to Alternative I. With respect to chemical treatments, this alternative is anticipated to have more adverse environmental consequences than Alternative I, but generally, we would not expect impacts to be significant because as previously stated all pesticides must be registered by EPA and must be found to not generally cause unreasonable adverse effects on the environment. However, without the added flexibility for die-off that is afforded under Alternatives I, III, IV-a, or IV-c, regions that potentially require a higher level of chemical treatment include A, B, C, L, R, T, and U (compare Figures 3.1-16 and 3.1-17 in Chapter 3.1.3.9 to Figure 1.7-4). If a future EPA-registered pesticide included a chemical that has the potential to result in the formation of THMs, we would expect long-term, sustained treatment of water sources may result in adverse, but not significant, impacts to water quality (see Chapter 3.1.3.10), and also result in adverse, but not significant long-term effects to biological/ecological

resources and air quality from chemical treatments. Based upon the EPA chemical registration process, studies are conducted to determine the environmental consequences of the proper use of chemicals, and the product labels for such chemicals contain information on the legally acceptable use of the chemicals. We would expect that the use of such chemicals will be in compliance with product labeling requirements as well as applicable laws, which are designed to protect from harm both the user of the chemical as well as the public at large. Through EPA's own analyses, and also based on the impermeance of the effects that these chemicals have to the environment, we expect the potential environmental impacts would not be significant.

The risk of adverse impacts to human health relating to the increased use of chemicals should not be significant and may be minimized as long as labeling requirements are followed, as the FIFRA registration process considers risk to human health and establishes handling processes that are appropriate to minimize such risks. The possibility of potential impacts from THMs to be formed may occur in regions that may require the highest treatments (regions A, B, C, L, R, T, and U, see above), but because transport of such toxins is not well known, these impacts cannot be well defined. Overall foodborne illnesses are expected to be reduced compared to Alternatives I, IV-a, III, and IV-c.

Alternative III.
As proposed (i.e., Alternative I), with an additional criterion establishing a maximum generic *E. coli* threshold

This alternative would be substantially similar to Alternative I; however, the implementation of a maximum threshold for generic *E. coli* may mean that there may be circumstances when a farmer is not able to account for microbial die-off and/or removal. Such circumstances, however, would be dependent on the numerical criterion of the threshold. Therefore, the likelihood that a farmer may decide to treat water is slightly higher than Alternative I or IV-a. It is, however, more likely that the farmer would first select to add a post-harvest step to account for additional die-off.

As stated above, all pesticides must be registered by EPA and must be found to not generally cause unreasonable adverse effects on the environment. As long as such products are used in accordance with their labeling requirements (the FIFRA registration process considers risks to human health), which would be a reasonably foreseeable use, we would expect any adverse environmental and human health impacts related to treating poor water quality to be considered not significant. Potential health effects to product users may be minimized through the proper use and handling of the product as discussed in this Chapter and in Chapter 4.1, including using protective equipment (e.g., chemically resistant gloves to protect against exposures). Potential health effects to those that consume water that may be contaminated with pesticides may be minimized through regular water testing and early identification of such products in the water supply (see Chapter 4.1 under the subheading for Human Health and Safety).

As compared to Alternatives I and IV-a, establishing a maximum threshold for generic *E. coli* may cause some growers in a region where the water quality is poorest to potentially shift from growing covered produce, but not to the degree that may occur under Alternative II or IV-b. These potential shifts are limited by the fact that existing marketing agreements in the most impacted regions already operate with more stringent water quality standards than what would be required under

Alternative III, and such agreements account for more than 80 percent of the produce that would be covered by the rule.

Alternative IV.
Alternatives for direct water application method

As previously stated, Alternative IV allows for the standards considered under Alternatives I through III to include root crops, such that agricultural water applied using a direct water application method would include root crops that are irrigated using low-flow methods (e.g., drip irrigation), where contact with the edible portion occurs below the soil surface. As considered in this analysis under Alternatives I through III, agricultural water would not be in direct contact with covered crops unless the edible portion of the crop was above the surface to some extent. An example includes carrots, where a portion of the vegetable and the edible greens would be above the soil surface. In other words, the analysis of Alternatives I through III assumes that they exclude root crops. Therefore, the impacts for each of those alternatives would be somewhat greater under Alternatives IV-a, IV-b, and IV-c due to the fact that more crops would be covered under the standards directed at agricultural water; however, the preferred management decision choices farmers may make under Alternatives IV-a, IV-b, or IV-c would be comparable to those identified under Alternatives I, II, and III.

As such, mechanism(s) to account for microbial die-off and/or removal is expected to be the preferred management decision under Alternative IV-a, and due to the added flexibility associated with this alternative, long term chemical treatment of agricultural water would not be necessary. Therefore, under Alternative IV-a, switching water source and ceasing to grow covered produce are not expected to be preferred management decisions.

Under Alternative IV-b, switching water source is expected to be the preferred management decision. In comparison to Alternatives I and IV-a (and to some extent Alternatives III and IV-c), this alternative would not have the added flexibility to account for microbial die-off and/or removal; therefore, farmers are more likely to decide to switch water sources, particularly away from surface waters to a cleaner source. Actions that may result in further groundwater drawdown would be expected to exacerbate the existing significant adverse conditions (i.e., potential subsidence and the related continued degradation of water quality). The regions that may be most affected are B, C, D, I, J, and U (compare Figures 3.1-16 and 3.1-17 in Chapter 3.1.3.9 to Figure 1.7-4), as well as corresponding areas in the northeastern and northcentral reaches of Mexico that share an aquifer with regions D, I, and J in the United States. These regions may also experience irreversible effects to soils. Therefore, these impacts under Alternative IV-b related to lowering the water table, deteriorating water quality, and land subsidence are considered significant adverse. In addition, Native American Tribes may be disproportionately impacted as groundwater drawdown could have potential environmental impacts including socioeconomic impacts related to access to water on reservations, particularly in regions B and J. Such impacts would also be considered significant adverse.

Under Alternative IV-b, there may also be a greater potential (as compared to Alternatives I, IV-a, III and IV-c) for the use of chemical treatments (as opposed to the management decision to switch to a cleaner water source) to bring water into compliance. Such actions are expected to

result in similar (but slightly greater) impacts under Alternative IV-b such that potentially adverse but not significant impacts would be expected to water quality, air quality, biological and ecological resources, and human health. Proper use, handling, and disposal of chemical treatment products in accordance with their labeling requirements (which would be a reasonably foreseeable use) would minimize potentially more severe environmental impacts.

Alternative IV-c is expected to have similar environmental impacts compared to Alternatives I and IV-a; however, the implementation of a maximum threshold for generic *E. coli* may mean that there may be circumstances when a farmer is not able to account for microbial die-off and/or removal. Such circumstances, however, would be dependent on the numerical criterion of the threshold. Therefore, the likelihood that a farmer may decide to treat water is slightly higher than Alternative I or IV-a.

Further, under Alternative IV-c, establishing a maximum threshold for generic *E. coli* may cause some growers in a region where the water quality is poorest to potentially shift from growing covered produce. These potential shifts are limited by the fact that existing marketing agreements in the most impacted regions already operate with more stringent water quality standards than what would be required under IV-c, and such agreements account for more than 80 percent of the produce that would be covered by the rule.

4.3 Subpart F / Untreated: Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste - Untreated Proposed § 112.56(a)(1)(i)

FDA's rationale for proposing Subpart F

It has long been recognized that pathogens can be introduced to fruit and vegetable production systems by the application of manures or sewage sludges as fertilizers (Schlech et al., 1983). Fecal material has been shown to contain human pathogens (Jiang and Shepherd, 2009; Kudva et al., 1998; Pell, 1997; WHO, 2006; Zhao et al., 1995), and the use of manure containing soil amendments as an agricultural input increases the likelihood that produce may become contaminated (Jiang and Shepherd, 2009). Soil amendments, partially composted manure, raw manures or teas made from such materials are potentially significant reservoirs of human pathogens.

Proposed Subpart F establishes standards directed to treated and untreated BSAs of animal origin and human waste. These standards include requirements applicable for determining the status of a BSA of animal origin; procedures for handling, conveying, and storing BSAs of animal origin; provisions regarding the use of human waste in growing covered produce; acceptable treatment processes for BSAs of animal origin applied in the growing of covered produce; microbial standards applicable to treatment processes; application requirements and minimum application intervals; requirements specific to agricultural teas; and records requirements (21 CFR Part 112).

Notwithstanding the associated health benefits from implementing the proposed BSA standards, FDA, in the 2014 supplemental proposed rule, removed the 9-month minimum application interval for use of raw manure in proposed § 112.56(a)(1)(i) (79 Fed. Reg. 58434). FDA is deferring its

decision on an appropriate time interval until it pursues certain actions, including a robust research agenda, risk assessment, and efforts to support compost infrastructure development, in concert with the USDA and other stakeholders (79 Fed. Reg. 58434).

Following the completion of the risk assessment and research work, FDA expects to (1) provide stakeholders with data and information gathered from scientific investigations and risk assessment, (2) consider such new data and information to develop tentative scientific conclusions, (3) provide an opportunity for public comment on our tentative decisions, and (4) consider public input to establish an appropriate minimum application interval(s).

With respect to this EIS, FDA determined it is still appropriate to evaluate the potential environmental impacts from implementing an application interval under proposed § 112.56(a)(1)(i) (including alternatives identified in Chapter 2.1) because FDA intends to finalize this provision at a future point in time. Such analysis has value in order to establish or improve upon the methodology for identifying environmental consequences, costs, and risks associated with implementing the action that FDA proposed in its 2013 proposed rule or one of its alternatives in the future, at a time when FDA has completed its research, risk assessment, and public outreach. Including the analysis further allows FDA to evaluate the cumulative potential impacts of the final action. At that time, it may be necessary to either update the ROD or prepare a NEPA re-evaluation or supplemental statement in accordance with 40 CFR § 1502.9(c), based on FDA's findings.

In terms of conducting the environmental impact analysis described in this document, FDA used available baseline data as provided by USDA's NASS Surveys as presented in Chapter 1.9 and 2.1 Subpart F; and information presented in Chapter 3.4 Waste Generation, Disposal, and Resource Use (as well as related environmental information with respect to water resources (Chapter 3.1), Soils (Chapter 3.3), and Air Quality and GHGs (Chapter 3.5). This information includes where raw manure is generated with respect to produce that would be covered by the PS PR, how raw manure is applied (also discussed in Appendix C), and regulations and industry guidance that govern the use and application rates of raw manure. Other information that was used to support our analysis includes the hazard classification, exposure assessment, and routes of contamination information presented in the Draft QAR (FDA, 2013c), and the related economic and foodborne illness discussions presented in the Preliminary Analysis of Economic Impacts (and supplemental) (FDA, 2013b and 2014b). Finally, other sources of information with respect to raw manure and potential pathways of contamination that leads to foodborne illness came from online information published by CDC (Chapter 1).

The following set of management decisions and alternatives applies to untreated BSAs of animal origin.

Management Decisions

The environmental impacts of standards directed to BSAs of animal origin and human waste - untreated are the result of management decisions a covered farm makes in order to comply with the standard. FDA has chosen to take a non-prescriptive approach when establishing standards under subpart F to allow for, and encourage, scientific advancement.

As discussed under Chapters 4.1 and 4.2, FDA, in coordination with USDA, identified the reasonably foreseeable actions, or management decisions, that businesses potentially affected by any final rule might take in order to come into compliance with, or to potentially avoid being subject to, the alternatives under consideration for inclusion in the final rule. Under subpart F, FDA and USDA identified the following actions: switch to a treated (composted) material, use BSAs of non-animal origin; use chemical fertilizers, comply with the requisite waiting period (applies specifically to each alternative), stop growing covered produce, and change the application method.

While the Final EIS addresses all reasonably foreseeable alternatives, FDA is aware that some management decisions will likely be more preferable to covered farms when a provision on untreated BSAs of animal origin (including an application interval) is finalized. In the interim, as FDA conducts a risk assessment and research to determine the appropriate application interval, it is difficult to identify which management decisions may be more preferable to covered farms. At such time as FDA finalizes a provision for standards directed at untreated BSAs of animal origin, the likelihood of operations taking certain management decisions will be reassessed based on the standard that is being finalized.

General background on resources related to the proposed provision

Much of the baseline information that is presented under this provision refers back to data presented in the No Action Alternative (Chapter 4.1) and the baseline data presented in Chapter 3. This section summarizes the relevant baseline data needed to assess the potential environmental impacts for subpart F, specifically proposed § 112.56(a)(1)(i) when finalized to establish an appropriate application interval.

Approximately 12.5 percent of produce farms use BSAs of animal origin, and of those only roughly 18.5 percent use untreated (raw) manure; this equates to approximately 821 farms nationally, or 2.3 percent of the covered produce farms covered by the PS PR (FDA, 2013b). The estimated total acreage of produce farms that apply untreated BSAs of animal origin is 70,134 produce acres or 1.56 percent of total produce acres (FDA, 2013b) (see Chapter 2.1, Table 2.1-4).

Harvest intervals relative to BSAs of animal origin

Few fast-growing produce crops have harvest cycles of 45 days or less from planting of seed; a list of such crops appears in Table 3.4-5. Most fresh produce crops have full summer planting to harvest cycles, varying between 45 days and 120 days. While parts of the U.S. only get one crop per year (notably the northeastern regions such as region R), other parts of the U.S. (notably the subtropical regions C and U) can achieve multiple (i.e., double or triple) cropping within one year. Another consideration is that some produce crops have multiple harvest cycles (e.g., perennials or biennials such as caraway, fennel, mints, young sorrel, and strawberry (Donezal, 1991), which could allow successive harvests in less than 45 days.

While most crops have a seed-to-harvest interval of approximately four months, intervals for application of BSAs of animal origin to crop harvest vary based on the applicability of federal law (i.e., organic regulations) and industry marketing agreements and when none exist or are not chosen to be followed, individual grower's decisions. USDA organic regulations have shorter application to harvest intervals (90/120 days), while some marketing agreements may have

application to harvest intervals of up to a year (Chapter 3.4.3.3). FDA found no data regarding whether BSAs of animal origin are commonly applied between the harvest intervals for crops with shorter seed-to-harvest durations (i.e., between double- or triple-cropping intervals), or if other soil amendments, such as chemical fertilizers, may be used during these periods.

Water Resources- Information on water quality and availability is important for establishing potential impacts under this provision.

Standards directed at BSAs of animal origin and human waste are not intended to have a direct impact on water resources. However, environmental effects may occur if as a result of the standards, BSAs are stored or applied in a manner that increases nutrient transport or by altering soil water content.

Produce-growing areas of the U.S. are routinely irrigated where natural rainfall does not supply optimal growing conditions, as discussed in Section 3.1 (more than half of vegetable production is from irrigated land). Runoff from precipitation or irrigation tail water (where flood and furrow practices are used) could contain excess nutrients leached or in the form of eroded soil particles that can enter surface water. The use of BSAs of animal origin over time increases the moisture capacity of soils that in turn would reduce the irrigation requirements of the crops.

Biological soil amendments of animal origin are potential vectors of pathogens harmful to human health. Soil water content is a factor that influences the survival rate of harmful pathogens (Abu-Ashour et al., 1993). Soil water content, however, is but one of many factors that influence pathogen survivability; others include soil physical and chemical properties, and normal atmospheric or climate conditions for the region. Water-soil interaction is discussed in greater detail in Chapter 3.3.

Indiscriminate storage, application, or disposal of BSAs of animal origin, irrespective of region, presents the possibility of contamination of both surface waters and of groundwater with harmful pathogens and other contaminants.

Depending upon how and when BSAs of animal origin are incorporated into soils, transport of nutrients and harmful pathogens may increase. For example, if a grower tills the soil after an untreated BSA application, there is a reduced chance that runoff will carry nutrients into surface water supplies. Conversely, if untreated BSAs are applied to the soil surface (such as during a fall application) and are not incorporated, there is a higher chance for harmful pathogens along with the nutrients associated with untreated BSAs (e.g., nitrogen) to contaminate surface waters and downstream biological receptors. Pathogen survival, however, is inversely correlated, meaning that incorporated pathogens survive for a longer period, while those present in unincorporated manures die off more rapidly due most likely to exposure to elements (such as desiccation and UV irradiation). The possibility of nutrient loss to runoff and erosion is greater with early fall application or winter application especially where late winter or early spring melt events result in runoff (Heartland Regional Water Coordination Initiative, 2006).

Water resources used for irrigation may have some indirect influence on pathogen survivability as well. For example, where furrow irrigation is involved, even in drier climates that receive less than

20 inches of rainfall per year, the moisture content of the soils may promote longer pathogen survivability in the soils; however, the filtering qualities of soils may restrict passage of those pathogens to the plant.

Harmful pathogens relative to the rule can persist in livestock and poultry. Regions where CAFOs operate and generate BSAs of animal origin relative to where covered produce is grown, include regions A, B, C, D, J, L, M, P, S, U, and V (See Figure 3.4-1).

Forty-five states regulate the application of BSAs of animal origin through nutrient management plans to help protect water quality by requiring proper application rates, thereby reducing the potential for adverse water quality impacts. States that do not require such plans include Alaska, Hawaii, Connecticut, Nevada, and Wyoming.

The wide range of waiting periods represented by the alternatives (0 to 12 months) increases the range of potential environmental impacts from the action. The most likely management decision to be chosen in order to comply with Alternative II (i.e., a waiting period of 0 days) would be a change in application methods, as the standard would still require that the BSA of animal origin must be applied in a manner that does not contact covered produce during application. The waiting period under Alternative III is identical to those required under the National Organic Program, and many farms that use untreated BSAs of animal origin would already be expected to be complying with the National Organic Program standard. Alternatives II and III would establish shorter waiting periods relative to the originally proposed Alternative I (decision subsequently deferred), which would mean that waiting the requisite time period would be more feasible. Alternatives I, IV and V, which would establish longer waiting periods of 9 months, 6 months, and 12 months, respectively, mean that management decisions that would result in switching to BSAs of non-animal origin, treated BSAs, or chemical fertilizers would be more attractive to growers. The potential impacts on water resources would depend on both the alternative and the management decision chosen.

As discussed previously, only 12.5 percent of all covered farms use any type of BSAs of animal origin, and only 2.3 percent of covered farms use untreated BSAs; most farms are already using chemical fertilizers. Therefore, the potential for increase in the use of chemical fertilizers is limited. When applied properly and given the small percentage of farms that could switch from untreated BSAs, adverse impacts to water resources would not be significant. Although switching to treated manure or BSAs of non-animal origin may have an impact on the crop yield, it is more likely that irrigation requirements are the limiting factor and would remain fairly constant since no additional water is required in the treatment or application process; therefore, as long as nutrient management plans are followed, there would be no impacts to water resources. The potential impacts on water resources, if farmers stop growing covered produce, are dependent upon the new use of the land. Such decisions are made by a farmer and may vary by year, the equipment and farm set-up the farmer has that could be used to manage a new particular crop (without incurring extensive capital costs), and many other factors. It would be speculative to try to assume what these decisions would be. Given the very small number of farms nationwide that may consider to

stop growing covered produce (approximately 821 farms nationwide, or 2.3 percent of all covered farms), we do not anticipate such impacts to be significant at a regional or national level.[20]

Comply with requisite waiting period
Increasing the storage time between applications could have an adverse effect on the quality of water resources as the potential for runoff becomes more likely over time, increasing the nutrient loads for nearby surface water sources. A mix of state and local agencies, working in concert with USDA conservation districts, oversee individual nutrient management plans for farms (including for CAFOs and farms that grow produce that would be covered by the rule). These plans, in part, provide application rates for efficient use of the product. Manure is typically managed to avoid over-application of target nutrients (nitrogen or phosphorus) as part of a strategy to support the Clean Water Act (CWA is regulated by EPA, but is often implemented or regulated at the state level). Time-of-year restrictions, application procedures including incorporation and setback distances, and other measures are primarily intended to avoid eutrophication of surface water and contamination of groundwater with limiting factor nutrients such as nitrogen and phosphorus.

Although the switch to a requisite waiting time may have an impact on which crops are grown, it is likely that irrigation requirements are the limiting factor and would remain fairly constant since no additional water is required, which would likely result in the nine-month waiting time having a moderate but not significant adverse impact on water resources due primarily to increases in nutrient runoff because impacts to water quality would not be sustained, and given the longer waiting time water conditions are likely to return to ambient conditions.

Change application method
If untreated BSAs of animal origin are injected directly into the soil, there is opportunity for less runoff into nearby waterways. Less runoff means better water quality, and a potential for improved watershed nutrient load into receiving waters. There may be an overall reduction in nutrient load to the ecosystem, which would be a low-level beneficial impact on both local and national levels.

Biological and Ecological Resources- These resources are part of a larger ecosystem and are affected by, and help determine, the quality of the natural environment.

Vegetation

BSAs of animal origin are used in farming operations to provide nutrients to agronomic crops. These nutrients, if allowed to interact with non-agronomic plants through direct application or runoff, will affect the growth and health of vegetation adjacent to application sites. Nutrient runoff into surface waters has the potential to cause algal blooms and other unwanted consequences. Algal blooms can result in die-offs in aquatic plant and animal species as well as other algal species due by limiting available sunlight or oxygen. They may also result in the production of toxins that can have adverse impacts on other species.

[20] Also note that 821 farms represents approximately 0.04 percent of all 2,109,303 farms nationwide.

Wildlife

The application of BSAs of animal origin have indirect impacts on wildlife through the nutrient uptake by vegetation and the resultant growth of this vegetation that provides food and shelter opportunities for wildlife species. The nutrient input to ecological systems may potentially alter the ecosystem, favoring one group of wildlife species over another. Untreated BSAs of animal origin potentially contain pathogens that may adversely affect wildlife species.

Wetlands

The quality of the water entering a wetland system would be adversely impacted if nutrient- or pathogen-laden BSAs of animal origin contaminated surface or groundwater sources. A change in water quality has the potential to impact wetland function and value (as a habitat). Many wetlands have the potential to filter and thereby improve water quality downstream of the wetland.

While nutrient runoff would play a significant role in the potential impacts on biological and ecological resources resulting from standards directed at untreated BSAs, these standards also have the potential to impact biological and ecological resources in other ways.

Switch to treated materials

The scale of a potential change (i.e., increased usage) from untreated to treated BSAs, relative to the current practice is unknown; however, the volume of treated BSAs, relative to current usage (most farms use chemical fertilizers or may be trending toward green manure or other practices) is not expected to increase substantially, given that only potentially 2.3 percent of all covered farms nationwide, at most, could be impacted. The proper application of treated BSAs would not adversely impact biological or ecological resources differently than the use of untreated BSAs.

Due to the application of dried material with reduced moisture content from composting, there is a potential risk of airborne and windblown material to have continued low adverse offsite impacts on receiving water bodies relative to the existing condition. The result of this may potentially contribute to a minimal degradation of overall water quality and may have short-term minimal impacts to aquatic organisms. Treated material, when dried, contains slightly more concentrated nutrients than untreated material, however, because the nutrients are more concentrated farmers need less of it to meet agronomic needs of the crop. Therefore, in terms of nutrient availability, a change to treated material would largely represent conditions that are similar to the existing condition. Dried material applied to the surface and not incorporated may be more easily transported to water bodies than untreated material. Such conditions could pose a slightly greater risk of water quality effects related to algal blooms and related issues such as eutrophication or the production of toxins that harm aquatic organisms including fish, amphibians, and insects. However, because a switch to treated material would be relatively similar to the existing condition, and only slightly more concentrated nutrient content from the treated material would be available for transport, water quality conditions and any impacted wetlands could be expected to return to ambient conditions in a relatively short amount of time. In addition, these impacts could be expected from a relatively low number of farms (approximately 2.3 percent of all covered farms nationwide). Because water quality would recover to ambient conditions, aquatic species populations and ecosystems could recover, and given the very low number of farms from which

such impacts could occur, we do not expect impacts to reach a level where it would be considered significant at a regional or national level.

Increased storage of BSAs of animal origin for composting or other uses where the untreated manure is produced could potentially lead to increases in off gassing and nutrient runoff. For some operations the effects of nutrient runoff may be minimized by adherence to the requirements of a facility's NPDES permit, where applicable, and/or requirements within the farm's nutrient management plan.[21]

Switch to BSAs of non-animal origin
The application of BSAs of non-animal origin would have no impact on vegetation or wildlife on a national level.

Switch to chemical fertilizers
As stated above, the use of chemical nutrients may have a potentially adverse effect on the environment, including the surrounding waters due to potential runoff if proper precautions are not taken. Excess nutrients from applications of chemical fertilizers in the form of runoff may flow into streams and enter water systems, causing damage to aquatic ecosystems that may include eutrophication and algal blooms. The improper storage of chemical fertilizers may also pose risks to biological and ecological resources, specifically surface and groundwater resources. If proper application and chemical storage precautions are not taken, the use and storage of chemicals may have a potentially adverse effect on the environment, including surrounding waters. However, we do not believe the improper use of chemical fertilizers to be a reasonably foreseeable use. Nutrient management plans place state-mandated requirements for farmers on their activities that are important for reducing impacts to water quality and soils, such as how best to apply and store all types of fertilizers including chemical fertilizers. As long as chemical fertilizers are used properly, water quality would be expected to return to ambient conditions.

Given the very small number of farms nationwide that may consider a switch from untreated BSAs of animal origin to chemical fertilizers (approximately 821 farms nationwide, or 2.3 percent of all covered farms), we do not anticipate the effects to the environment from such a switch to rise to a significant impact at a regional or national level.

Comply with the requisite waiting period
Nutrients or other contaminants associated with the improper storage of BSAs of animal origin may make their way into surface or groundwater resources, indirectly impacting ecosystems. If excessive amounts of BSAs of animal origin are applied in a single application event (to use up stored BSAs of animal origin), aquatic organisms, including fish, amphibians, and insects, may be adversely impacted by reduced water quality as a result of contaminants (nutrients, pathogens, etc.) being introduced into surface waters. Increased storage times could potentially lead to increases in off gassing and nutrient runoff as well as a reduction in nutrient availability. Nutrient management plans place state-mandated requirements for farmers on how best to apply and store fertilizers. Storage requirements for the observed waiting period may pose a burden to farms, but we expect that the very small number of farms affected will minimize impacts and also in increase

[21] More information on NPDES permits is found in Chapters 3.1.2, 3.4.2, and 4.1.

the likelihood of adopting new infrastructure to store the material or otherwise dispose of excess animal waste (e.g., sell to other farms or to composting facilities). Therefore, impacts are not expected to be significant at a regional or national level.

Stop growing covered produce
The change from one crop to another may have beneficial impacts on biological and ecological resources. Changing from covered produce to non-covered produce may be beneficial because, similar to crop rotation, changing crops provides for a form of natural pest reduction through diversity. When the same type of crop is grown in the same field repeatedly, pest populations of that crop tend to build up, sometimes to levels that require chemical inputs above those used for past crops. Crop diversity is a part of the preventive pest management program (PMP); therefore switching to a non-covered produce may reduce the amount of chemical inputs, which may have a low beneficial impact on biological and ecological resources.

Change the application method
If untreated BSAs of animal origin are applied directly to the soil surface or injected directly into the soil, there is opportunity for less runoff into nearby waterways. Less runoff means fewer algal blooms, better water quality, and a potential for improved watershed nutrient load into receiving waters. There may be an overall reduction in nutrient load to the ecosystem, which would provide limited beneficial impacts to receiving water bodies and biological and ecological resources, but which are not considered to be significantly beneficial at a regional or national level.

Soils- For decades, chemical fertilizers have been an essential component in the production of crops used for food. Use of chemical fertilizers peaked in the early 1980's and dropped when the largest users (grain growers) lost some market demand for grain. Since that time fertilizer prices have fluctuated, but generally remain consistent with the fluctuation in energy prices. More recently, U.S, farmers have moved toward single-nutrient fertilizers that contain a relatively high level of a certain nutrient needed specifically to enhance a soil quality or crop requirement (USDA ERS, 2013c).

While chemical fertilizers are useful for adding certain depleted nutrients to an agricultural field, if not properly applied, excess chemicals may leach to groundwater, enter tailwaters, or generally runoff into receiving surface waters. Chemical fertilizers, without the application or in-field production of adequate carbon inputs (e.g., cover crops), do not maintain good soil health, as they do not contribute to building healthy soil structure and microbial communities (see Chapter 3.3.3.6 and USDA NRCS, 2013a; Brady and Weil, 2002; Magdoff and van Es, 2009).

USDA organic regulations limit the use of chemical fertilizers for certified organic farmers.

The use of BSAs of animal origin is an effective way to improve the nutrient availability, structure, and overall health of agronomic soils. However, the use on produce farms is limited as previously discussed. Where BSAs of animal origin are used, manure application rates are generally determined by an analysis of the available nitrogen of the soil and the nitrogen needs of the crop to be grown, which predominantly may be region-specific due to a number of environmental, climate, geologic, and other factors. Forty-five states require nutrient management plans (see Chapter 3.3 and 3.4) that govern the application rates of untreated manure and other products; the

goals of such nutrient management plans include reducing erosion and helping states meet TMDL requirements (Chapter 3.1).

The impact of standards directed at untreated BSAs of animal origin will primarily be influenced by the length of the requisite waiting period.

Switch to treated material
Treated manure may reduce the amount of nutrients available for plant uptake, compared with untreated manure. Treating manure also reduces manure mass, and treatment results in less material to transport and apply to cropland. Efficient use of manure as a soil amendment is dependent on the nutrient requirement of the crop and the time when the nutrient is needed. About 25 percent of the dry matter from composted cow manure is in the form of ligno-proteins, a marriage of lignins and proteins. As a result, treated manure is very stable, and decomposes slowly (Goldstein, 2001). Therefore, composted manure may also become a soil builder. No significant impacts to soils are anticipated as a result of the use of treated materials.

Switch to BSAs of non-animal origin
The grower may need to replace nutrient and soil enhancing capacity of BSAs of animal origin by implementing the following strategies: working in a cover crop rotation, using high-residue crop or perennial sod to add SOM from plant material, reducing tillage and the use of bulky organic amendments for both organic matter and plant nutrients, and adding nitrogen-based fertilizer with an added source of carbon. As with the use of treated manure, the amendment still requires testing to verify concentrations of nutrients are commensurate with soil requirements or to determine application rate. A nutrient management plan would generally provide requirements for applying fertilizers that minimize the overuse of fertilizers and to provide beneficial effects to soil health while ensuring proper soil function is retained. We would reasonably expect farmers to implement proper application rates and verify proper nutrient content of the soil amendment. Therefore, we would not expect significant impacts to soil as a result of implementing this management decision.

Switch to chemical fertilizers
The use of synthetic fertilizers can accelerate the rate of organic matter decomposition directly, depending on various factors, but more importantly synthetic nitrogen fertilizer only adds nitrogen, but no carbon compounds, which are important for maintaining soil organic matter levels. Without commensurate carbon additions (e.g., cover crops) to the system, soil organic matter levels and soil health will degrade.

Any degradation of soil can have long-term adverse impacts, which may be reversible through the application of organic matter to the soil in addition to the chemical fertilizers. The proper application of nutrients and organic matter would result in no significant impacts to soil function and the soil's ability to filter nutrients, water, and pathogens properly. Without the application of organic matter, e.g., incorporation of cover crops, then the long-term use of synthetic fertilizers, indirectly through lacking organic additions, may have a significant adverse impact on soil structure, which may not be reversible under such conditions because the soils' resistance to erosion may be too severely degraded.

Comply with requisite waiting period
Longer waiting periods, such as 6, 9 or 12 months, may have a beneficial impact on soil structure because such waiting periods may result in a decreased frequency of disturbances to the soil associated with plowing or turning. The grower can employ strategies to reduce the impact of the waiting period on soil nutrient levels by utilizing treated compost, green manure and cropping rotation, commercial fertilizer, or a combination of all schemes. If the application of chemical fertilizer is the only adaptive strategy utilized, then the potential for adverse effects on soil are increased, as discussed under the management decision titled S*witch to chemical fertilizers*, directly preceding this management decision.

Cease growing covered produce
The impacts on soil resources associated with ceasing to grow covered produce would depend on what crops were grown in its place, if any. It is anticipated that growers would choose alternative crops with similar management practices such that proper soil function would be retained and there would be no significant impacts to the soil resources.

Change application method
This management decision is likely regardless of the application interval that is ultimately finalized as the standard in § 112.56(a)(1)(i). Regardless of the application interval, any final regulation (after FDA completes its robust research agenda, risk assessment, and outreach) is anticipated to specify that the untreated BSA must be applied in a manner that does not contact covered produce during application.

Soil structure and quality would continue to be disturbed or decomposed, similar to baseline conditions. Providing that proper soil function is maintained, then the overall effect to soils would remain largely unchanged from present practices. Therefore, a minimal but not significant impact to soils would be expected.

Waste Generation, Disposal, and Resource Use- The application of BSAs of animal origin to farm fields provides valuable nutrients and organic matter to the soil, and also provides a mechanism for the beneficial use of manure and other animal-derived by-products. Although the available data do not allow for a determination of which farms nationwide use untreated BSAs of animal origin, we have analyzed the regional locations of livestock and poultry operations in relation to produce growing regions (see Chapter 3.4.3.1) and determined that covered produce growers located in regions A, B, C, D, J, M, L, P, S, U and V are located in proximity to livestock and/or poultry operations and therefore sources of available BSAs of animal origin.

GAPs recommend that raw manure or biosolids application not occur during the growing season, but rather that it occur in fall or in spring prior to planting. GAPs also recommend incorporation of manure or biosolids into the soil to promote competition from ambient soil microbes and facilitate die-off of pathogens and enteric bacteria.

BSAs of animal origin are normally applied before planting, at the time of planting, and/or once the crops are harvested (typically in the fall). The most common method that BSAs of animal origin are incorporated into soils is through plowing or turning the soil in (e.g., disc and harrow),

though an increasing number of growers are employing no-till methods that allow BSAs to incorporate naturally into the soils media (typically in the fall, after harvest).

As discussed in Chapter 3.4, there are some short-season crops (Table 3.4-6) with growing to harvest cycles of 45 days or less; however, most crops have a growing cycle of about three to four months. Growing schedules and nutrient management are normally closely coordinated to ensure soils and plants have the proper amount of nutrients needed to meet projected crop yields.

A majority of BSAs of animal origin are generated either on the same produce farm where they are applied or on a neighboring or nearby farm. Untreated manure is prohibited entirely on certain crops intended for human consumption in some states. In addition, untreated manure is controlled or regulated to a certain extent by some industry growers associations (marketing agreements) and USDA organic regulations, either by disallowing its use entirely for the prior year or by requiring an application to harvest interval of 3-4 months duration, depending on the type of crop. These restrictions are in place to allow natural abatement and pathogen reduction to occur and to prevent raw manure application during the growing season. However, not all growers adhere to those practices, and such practices do not apply to all produce grown but are limited to either organically grown produce or specific commodities.

Switch to treated materials

More farms that would grow produce covered by a final rule already use treated BSAs of animal origin than do farms that use untreated BSAs of animal origin, if they use any BSA at all (most farms use chemical fertilizers or may be trending toward green manure or other practices). Composting (including the various methods to treat waste) is a common practice nationwide, but presently not all composting operations follow specified, scientifically proven GAPs or industry guidelines to ensure the elimination of harmful pathogens. Assuming the treatment process is approved and effective for eliminating harmful pathogens, and that any increase in storage requirements are easily met, such as through the adoption of new infrastructure (if required) to handle any excess volume of BSAs of animal origin, then there would be no significant impacts associated with waste generation.

If farmers switch to treated BSAs of animal origin and the nitrogen availability is unknown or difficult to predict, then regular testing would be required to allow farmers to properly apply BSAs of animal origin to meet agronomic needs and environmental goals (such as those in nutrient management plans). While the current factors may be adequate for general estimating of typical manure nitrogen availability, more precise estimates of nitrogen availability based on compositional analyses are needed to guide producers toward economical and environmentally benign application rates when using treated manures (University of Wisconsin-Madison, 2014). Chapter 3.3 and 3.4 discusses treated BSAs of animal origin in more detail; and Chapter 4.4 identifies impacts associated with treated BSAs of animal origin.

Switch to BSAs of non-animal origin

BSAs of non-animal origin would consist primarily of green manuring. Green manure is a crop that is grown then plowed into the soil or otherwise left to decompose for the purpose of soil improvement (e.g., clover, rye or soybeans). Use of green manure is effective at building soil organic matter. Green manure is discussed in greater detail in Chapter 3.3 Soils. BSAs of non-

animal origin may also include decomposed plant compost, mulch, and detritus, peat moss, or other plant-based materials.

On a national basis the change in management practices to include more non-animal natural soil amendments would affect a small number of covered farms (approximately 821 covered farms nationwide, or 2.3 percent of all covered farms) and result in only slight shifts in overall animal waste management practices, which are not expected to result in considerable difficulties for farms in storing, using, or disposing of excess animal waste. Therefore, any potential adverse environmental impacts are not expected to be significant with regard to Waste Generation, Disposal, and Resource Use.

Switch to chemical fertilizer
On a national basis the change in management practices to include more synthetic fertilizer soil amendments would affect a very small number of covered farms (approximately 821 farms nationwide or 2.3 percent of all covered farms) and result in only slight shifts in overall animal waste management practices, such that a shift from using BSAs of animal origin to using chemical fertilizers may increase the requirements for animal waste generators to manage any excess manure. Given the very small impact on the resource use, we do not expect considerable difficulties for farms in storing, using, or disposing of excess animal waste at a regional or national level. Therefore, any potential adverse environmental impacts are not expected to be significant with regard to Waste Generation, Disposal, and Resource Use.

Comply with the requisite waiting period
BSAs of animal origin are normally applied before planting, at the time of planting, and/or once the crops are harvested (typically in the fall). The most common method that BSAs of animal origin are incorporated into soils is through plowing or turning the soil in (e.g., disc and harrow), though an increasing number of growers are employing no-till methods that allow BSAs to incorporate naturally into the soils media (typically in the fall, after harvest).

As discussed in Chapter 3.4, there are some short season crops (Table 3.4-6) with growing to harvest cycles of 45 days or less; however, most crops have a growing cycle of about three to four months. Growing schedules and nutrient management are normally closely coordinated to ensure soils and plants have the proper amount of nutrients needed to meet projected crop yields.

The reduced frequency of application under Alternatives I, IV and V would result in increased storage time for BSAs of animal origin prior to their application to farm fields. Storage facilities would need to be constructed where they do not currently exist and managed in a way that prevents nutrients and other contaminants from entering the ecosystem. Because a very small number of covered produce farms currently use untreated BSAs of animal origin, we do not expect there to be considerable difficulties for farms in storing, using, or disposing of excess animal waste at a regional or national level. Therefore, any potential adverse environmental impacts are expected to be minimal and not significant with regard to the overall impact to Waste Generation, Disposal, and Resource Use.

Facilities that may store raw manure and may perform composting operations (e.g., CAFOs) are sometimes required to apply for a NPDES permit. Therefore, if the facilities are operated and

maintained in accordance with their permits (where applicable), under normal circumstances there are processes in place to protect against adverse harm to the environment (effects from runoff).

Cease growing covered produce
Changing from a covered produce crop to a crop that is not affected by the PS PR would allow the use of BSAs of animal origin, in compliance with other federal, state, and local laws and regulations. Selecting this management decision would represent the status quo in terms of use of BSAs of animal origin; therefore, because there would be no relative change in storage, use, or disposal of animal waste, there are no expected impacts to the resource.

Change application method
Application methods for BSAs of animal origin are discussed in greater detail in Appendix C and in Chapter 3.4. Land application of animal manure is an efficient utilization of BSAs of animal origin because of usually lower costs compared to treatment, and due to the nutrient benefits derived by crops from the manure. The most common land-application methods include surface spreading and subsurface injection. These methods are by-and-large accompanied by soil testing to establish soil fertility levels, testing the BSAs of animal origin for nutrient content, and establishing the proper selection of the application rate and method to ensure not to exceed crop nutrient requirements and to avoid soil and water contamination.

Other forms of manure application include broadcasting, banding, or shallow injection methods. These methods are further described in Appendix C in terms of defining their application method approach and timing.

A change in the application method of BSAs of animal origin is expected to have no impact on the storage, use, or disposal of animal waste, as the same quantity of BSAs would be used, just in a different manner.

Air Quality and Greenhouse Gases- As described previously, a very small proportion of covered farms are currently using BSA's of animal origin (approximately 821 farms or 2.3 percent of covered farms). General air quality conditions relate to manure storage and application, especially in terms of odor experienced, with odor representing both a short-term and localized condition.[22]

As illustrated in Figure 3.5-2 (Chapter 3.5), more than 80 percent of covered produce is grown in just five regions: B, C, D, L and U (see Figure 1.7-4). With regard to concentrated areas of covered farms, California currently demonstrates the poorest air quality, with several non-attainment areas for PM_{10}, $PM_{2.5}$, and ground level ozone (see Figures 3.5-3, 3.5-4, and 3.4-7 in Chapter 3.5). Greenhouse gas emissions from cropland agricultural soil management (see Figure 3.5-10 in Chapter 3.5) and manure management (see Figure 3.5-11) are moderate to high in regions B, C, D, and U, and are particularly severe in California.

[22] Note that there are some exceptions to the longevity of odor experienced where covered produce and livestock-producing manure operations are co-managed, and odor relates to longer-term storage of the animal waste. This is an existing condition that is not impacted by the rule.

BSAs of animal origin application practices are often augmented with chemical fertilizers, which also lead to short-term increases in emissions (e.g., N_2O). Transportation of manure further contributes to local, short-term air quality increases in greenhouse gases, PM, and ozone precursor gases.

Many of the management decisions have the potential to influence greenhouse gas emissions as discussed below. The exception is if farmers were to stop growing covered produce, as land management practices related to the application of BSAs of animal origin would likely be similar to the existing condition. When attempting to avoid the need to comply with the provisions of the PS PR, if finalized, growers would likely switch to crops with similar management requirements. Minimal changes in management of agricultural land may result in changes in emissions of criteria pollutants and major greenhouse gases; however, the changes in air quality and GHGs are not anticipated to be significant because farms are expected to switch to crops with similar management requirements.

Switch to treated material

The potentially greater impacts to air quality as a result of switching from untreated BSA's to treated (composted) material would primarily involve changes in manure management (see Figure 3.6-11 in Chapter 3.6) and agricultural soil management practices (see Figure 3.6-14) practices.

An increase in the storage of manure (e.g., compost piles) would be expected under this mechanism of complying with the provisions of the PS PR, if finalized, resulting in potential increases of windborne particulate matter, ozone precursor gases, and GHG emissions (primarily methane but also nitrous oxide). Changes in GHG emissions from unused manure would vary depending on how this manure is treated or stored. Nitrous oxide emissions can increase due to these changes in agricultural soil management practices. Finally, any increase in transportation of manure to on- or off-site storage or composting facilities could cause increases in CO_2 emissions from fuel combustion, although changes in emissions are expected to be relatively minimal and not significant since the transportation of manure would likely not require long-distance travel due to the high costs associated with shipping manure long distances. Additionally, farmers may rely on chemical fertilizers or BSAs of non-animal origin to augment their cropland soils due to reduced application of BSAs of animal origin (see below).

Switch to BSAs of non-animal origin

Overall, decomposing plant matter would contribute to SOC and atmospheric CO_2 once released (during tillage or possibly harvest). These contributions, given the very small numbers of growers that may switch to this practice on a nationwide scale, will result in no significant impact to air quality and no public health concerns related to air quality.

An increase in the storage or disposal of manure (including such treatments as the use of compost piles) would be expected as a result of switching to BSAs of non-animal origin, resulting in potential increases of windborne particulate matter, ozone precursor gases and GHG emissions (primarily methane but also nitrous oxide). Changes in GHG emissions from unused manure would vary depending on how this manure is treated or stored. However, considering the very small scale at which GHG emissions could be generated, which is relative to the very small number of growers

nationwide that could be anticipated to make a switch to BSAs of non-animal origin, such impacts are not significant.

Use chemical fertilizers
The major impacts to air quality as a result of switching to chemical fertilizers would involve changes in manure management (see Figure 3.5-11 in Chapter 3.5) and agricultural soil management (see Figure 3.5-14) practices. Reliance on chemical fertilizers can lead to increases in N_2O emissions from changes in agricultural soil management practices. Agricultural soil management, including large additions of chemical fertilizers, represents the greatest individual source of agricultural GHG emissions in the U.S. (see Figure 3.5-13). An increase in the storage or disposal of manure (e.g., compost piles) would be expected under this mechanism from excess manure accumulation, resulting in potential increases of windborne particulate matter, ozone precursor gases and greenhouse gas emissions (primarily methane but also nitrous oxide). This may potentially cause a localized minimal adverse impact on air quality, but such impacts are not expected to result in air quality related public health concerns at a regional or national level due to the very small number of farms nationwide that potentially may make such a management decision.

Comply with requisite waiting period
An increase in the storage of manure would be expected under longer application intervals, potentially resulting in increases in emissions of windborne PM, ozone precursor gases, and GHGs (primarily CH_4 but also N_2O). Changes in GHG emissions from unused manure will vary depending on how manure is treated or stored (short-term or long-term in nature). Some growers may choose to augment their fields with chemical fertilizers due to the nine-month application interval, resulting in potential increases in agricultural soil management-related nitrous oxide emissions.

As illustrated in Figure 3.5-2 (Chapter 3.5), more than 80 percent of covered farms occur in just five regions, which are B, C, D, L, and U (See Figure 1.7-4). With regard to concentrated areas of covered farms, California (region C) currently demonstrates the poorest air quality, with several non-attainment areas for PM_{10}, $PM_{2.5}$, and ground level ozone (see Figures 3.5-3, 3.5-4, and 3.5-7 in Chapter 3.5). Greenhouse gas emissions from cropland agricultural soil management (see Figure 3.5-14) and manure management (see Figure 3.5-11) are moderate to high in regions B, C, D, and U, and are particularly severe in California.

To put this regional analysis in perspective, the estimated 35,503 covered farms (covering 4,473,575 acres) represent just 1.70 percent of the total number of U.S. farms and 0.49 percent of total U.S. farm acres (FDA, 2014b). Given the very small percentage (2.3 percent) nationwide of covered farms that presently use untreated BSAs of animal origin, any adverse air quality impacts are not expected to result in public health concerns at the regional or national level, and are therefore not expected to be significant.

Change application method
Because growers would be switching to an application method that is not likely to contact edible portions of covered produce, manure management practices would likely remain similar to the existing condition. The particular application method employed would depend on the nature of the

manure. Solid manure can be applied directly to the soil surface, and better incorporation of the manure into the soil can reduce indirect emissions of N_2O due to volatilization as well as emissions of NH_4, an important precursor of particulate matter generation. Injection of liquid manure beneath the soil surface can also greatly reduce indirect nitrous oxide and ammonia emissions (eXtension 2012a).

Due to the small number of covered farms currently using BSA's of animal origin relative to total U.S. farms, and the fact that these farms would not dramatically change most management practices under this mechanism, it is anticipated that there would be no impact to air quality on a regional or national level. However, changing application methods could result in a minimal beneficial environmental impact that is not significant in regions where covered farms and associated livestock operations are more concentrated (i.e., regions C, D, U, and B (see Figure 3.4-1) due to reductions in particulate matter and nitrous oxide emissions.

Socioeconomics and Environmental Justice- Impacts that are associated with meeting the requirements of the provision for BSAs of animal origin could stem from economic costs to comply with any such final provision (related costs originally estimated at $9.2 million annually). Based on comments received on the 2013 proposed rule, however, FDA has removed the 9-month application interval related to use of raw manure from the PS PR and deferred its decision until FDA pursues certain actions. See Chapter 2.1 for a detailed discussion of FDA's proposed deferment of this provision. When FDA does choose to finalize this provision, the management decisions and the socioeconomic impacts resulting from these decisions and any economic costs would need to be evaluated in the aggregate, i.e., considering the implementation of all the provisions associated with the PS PR. A management decision and the associated environmental impacts would not likely be sufficient to result in changes that could impact employment or result in loss of income. Therefore, socioeconomic and environmental justice issues are addressed in aggregate under Chapter 4.7.

Human Health and Safety- The provisions that would establish a minimum application interval to untreated BSAs are intended to decrease potential pathogen contamination and would have a beneficial impact on human health and safety due to a reduction in exposure to pathogens although the level of significance will be determined by the alternative chosen. The alternatives considered range from 0 days to 12 months for untreated BSAs with a greater time interval leading to a greater reduction in potential pathogen contamination. FDA has indicated its intent to defer finalization of this provision until it pursues certain actions, including a robust research agenda and risk assessment, among other activities. It is too early to know the outcome of this research but it may be possible to identify a waiting period or a combination of requirements inclusive of a waiting period beyond which there is no significant increase in public health benefit.

Switching to treated materials, BSAs of non-animal origin, chemical fertilizers, waiting periods of all length, and changes in application method that minimize direct contact with covered produce are all expected to have a beneficial environmental impact on human health and safety due to a reduction in exposure to pathogens, although the waiting period will determine whether the impact is significant. Since very few farms (i.e., 2.3 percent of covered farms or 1.56 percent of total produce acres) utilize untreated BSAs of animal origin, the impact on human health would be limited to those who consume produce from this limited subset of produce farms. The use of

chemical inputs has the potential to create an adverse impact to human health (worker safety in particular); however, any impacts would be minimized by adhering to the requirements for label directions for storage, mixing, and application, for which we consider a reasonably foreseeable use. Longer application to harvest intervals such as those in Alternatives I, IV and V may result in some portion of farmers reducing the number of crop rotations within a year, which could reduce the amount of produce grown; however, any such reduction would be expected to be stabilized by market forces (i.e., other growers, regionally, locally, and internationally, would fill any gaps in supply).

4.3.1 Alternatives Analysis

This section provides a comparison of alternatives that FDA considered under Subpart F/ Untreated, and relates the potential environmental impacts from a grower that may select a particular management decision, as discussed at the beginning of this section.

Each of these alternatives is expected to have a beneficial impact on human health and safety. Despite the limited number of covered farms utilizing untreated BSAs of animal origin, the use of the resource is an important factor in contributing to illnesses. FDA has determined that the anticipated number of illnesses prevented associated with this provision would be substantially similar to the number of illnesses prevented that are associated with the other potentially significant provisions (FDA, 2013b). In addition, there are populations who choose to exclusively consume organically grown produce and therefore would be beneficially impacted by the alternatives.

Alternative I.
Minimum application interval of 9 months
Given the long interval between application and harvest, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period.

If farmers switch to treated manure and the nitrogen availability of the treated manures is unknown or difficult to predict, then regular testing would be required to allow farmers to properly apply manure to meet agronomic needs and environmental goals (such as those in nutrient management plans). While the current factors may be adequate for general estimating of typical manure nitrogen availability, more precise estimates of nitrogen availability based on compositional analyses are needed to guide producers toward economical and environmentally benign application rates when using treated manures (University of Wisconsin-Madison, 2014). The same testing is also required for untreated manure but not for synthetic fertilizers with a known nutrient content. With proper management, no adverse impact to soil health will occur.

The treatment of raw manure will require additional time, possibly creating a need to store manure. The storage of partially processed manure may lead to impacts to surface and groundwater; however, best management practices can reduce the potential for these impacts. In addition, if the storage of manure may occur at a facility that operates under a NPDES permit, where applicable, and provided the facility is managed in accordance with permit requirements, we would not expect significant adverse impacts.

The treatment process will require additional inputs in the form of energy, transportation, and money relative to the use of raw manure.

Given the small number of farms that use untreated BSAs of animal origin (estimated at 821 covered farms, or 2.3 percent of covered farms nationally) that could possibly switch to chemical fertilizers, the overall impacts to the environment would not rise to a significant impact at a regional or national level. The proper use and handling of chemical fertilizers, and adherence to manufacturer's recommendations to use of chemical fertilizers according to label directions, which is reasonably foreseeable, would result an expected return of water quality to ambient conditions. Moreover, excess use of chemical fertilizers are costly and adversely affect crops, and would not be consistent with state nutrient management plans.

Chemical fertilizers lack the organic matter that manure otherwise provides, thereby reducing soil structure and health. Therefore, the use of chemical fertilizers could cause moderate, but not significant, adverse environmental impacts to soils. Current trends show that other practices such as green manuring, no-till practices, and use of cover crops are growing in popularity. To the extent that these practices are adopted by the agricultural industry, they would help to control the magnitude of the adverse environmental impacts.

The production and transport of chemical fertilizers is not expected to have a significant adverse impact on energy use. As discussed throughout this chapter, any changes to the generation of air emissions would not differ substantially from the existing condition and would not rise to a level that would result in human health concerns at a regional or national level. Therefore, impacts related to air quality are not expected to be significant.

If growers choose to comply with the 9-month interval instead of changing the soil amendment type or application method, a minimal but not significant adverse impact is expected to result from the growing regime or from a reduction in the number of crops a farmer may harvest due to the small number of farms nationwide that would be impacted. There may be some reduction in farm income if farms need to set aside land or build structures to store the untreated BSAs of animal origin. The amount of produce may be reduced due to a reduced number of harvests per year based on a 9-month waiting period. This may cause an increase in the price of certain produce if supply is reduced and demand is high. However, this reduction in harvests would be expected to be stabilized by market forces (i.e., other growers, regionally, locally, and internationally, would fill any gaps in supply). Similar effects would be expected if growers stop growing covered produce, as regional produce commodity prices could potentially increase resulting from a decrease in supply in any particular region; however, we expect that demand for a certain produce commodity would eventually be met by other growers in the region, growers in other regions (commodity and environment specific), or international suppliers.

Alternative II.
Minimum application interval of 0 days
This alternative is similar to the baseline condition. Currently, there is not a regulated interval for the use of raw manure. However, this alternative would not allow for direct contact with covered produce during application.

If a farmer is allowed to use an interval of 0 days between the application of raw manure and harvest, there is no regulatory need to treat raw manure, switch to a BSA of non-animal origin or chemical fertilizer, or to cease growing covered produce. Therefore, changes in the type of soil amendment used or crop grown are not anticipated as a result of this management decision. Complying with the 0-day waiting period could require a change in application method for those farms that currently surface apply BSAs of animal origin, as they would need to ensure it does not contact the covered produce during application.

Changing the application method to prevent the contact of raw manure with a covered produce crop will potentially require the acquisition of additional equipment. This will require the outlay of funds for the purchase of new equipment and its ongoing maintenance. However, we do not expect a loss of income or employment to result at a significant level on a regional or national level due to the small number of farms potentially affected.

Minimal public health benefits may occur over the present conditions for farms that may be using a zero day application rate.

Alternative III.
Application interval consistent with organic regulations (less restrictive than Alternative 1)
With the exception of the short season crops listed in Table 3.4-5 with growing to harvest cycles of 45 days or less, most crops have a growing cycle of about three to four months. For such crops, no changes would be required to management practices in order to comply with this application interval. Additionally, farmers currently in the USDA organic program have already adapted their growing practices to be in compliance with this alternative. If a certified organic grower chooses to treat raw manure, the grower will be limited in the choices for treatment in order to maintain its organic status. The small percentage of covered farms which utilize untreated BSAs, as well as the high likelihood that such farms are certified organic growers, indicates that few farms would need to change practices in order to comply with this application interval. No significant impacts are associated with any management decision under this alternative.

Other farms that may be associated with marketing agreements that have more stringent application intervals may continue to observe their established standards if they are more stringent than what FDA proposes.

Some additional public health benefits may occur over the present conditions for farms that may be using a zero day application rate. The switch to a longer application rate to harvest interval may result in more (unquantified) foodborne illnesses prevented over Alternative II, but still fewer than what is estimated for Alternative I.

Alternative IV.
Minimum application interval of 6 months
As with Alternative I, given the long interval between application and harvest, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period. We would expect proper nutrient management, e.g., proper storage, nutrient

management plans, careful selection of application methods, and use of chemical fertilizers according to label directions, will limit any adverse impact to a level that is not significant. With proper use of chemical fertilizers, water quality would be expected to return to ambient conditions.

If farmers switch to treated manure and the nitrogen availability of the treated manures is unknown or difficult to predict, then regular testing would be required to allow farmers to properly apply manure to meet agronomic needs and environmental goals (such as those in nutrient management plans). While the current factors may be adequate for general estimating of typical manure nitrogen availability, more precise estimates of nitrogen availability based on compositional analyses are needed to guide producers toward economical and environmentally benign application rates when using treated manures (University of Wisconsin-Madison, 2014). The same testing is also required for untreated manure but not for synthetic fertilizers with a known nutrient content. With proper management, no adverse impact to soil health will occur.

Chemical fertilizers lack the organic matter that manure otherwise provides, thereby reducing soil structure and health. Therefore, the use of chemical fertilizers could cause moderate, but not significant, adverse environmental impacts to soils because reductions in soil structure and health are likely to be reversible from practices such as green manuring, no-till practices, and use of cover crops. These practices are growing in popularity and are effective at restoring soil health. To the extent that these practices are adopted by the agricultural industry, they would help to control the magnitude of the adverse environmental impacts.

The production and transport of chemical fertilizers may have an adverse but not significant impact on energy use and air quality because the resource use is not expected to change substantially as compared to current baseline conditions and, therefore, the impacts to public health from air emissions would not rise to a significant impact at a regional or national level (see Chapter 2.1 subpart F, Chapter 3.4, and Chapter 4.3).

Changing the application method to prevent the contact of raw manure with a covered produce crop during application may require the acquisition of additional equipment, which would equate to a one-time outlay of funds for the purchase of new equipment and its ongoing maintenance, and thereby cause a potential minimal (not significant) adverse environmental impact related to the socioeconomic resource component.

Similar to Alternative I, if growers chose to switch to a non-covered crop, regional produce commodity prices may increase, resulting from a decrease in produce grown in any particular region; however, demand for a certain produce commodity may eventually be met by other growers in the region, growers in other regions (commodity and environment specific), or international suppliers.

This alternative may result in improved public health benefits over Alternative II or III but less than Alternatives I or V, due to the longer application-to-harvest interval. However, in establishing the regulation in 7 CFR 205.203(c)(1) (reflected in Alternative III), AMS acknowledged that the raw manure standard is based on organic crop production practices and is not a public health standard (see 79 FR 58434 at 58459).

Compared to Alternative I, this alternative is expected to have slightly lesser impacts.

Alternative V.
Minimum application interval of 12 months

As with Alternatives I and IV, given the long interval between application and harvest, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period. Switching to treated material would reduce the interval between application of the treated manure and harvest to 0 days, rather than the interval of 12 months for the use of raw manure. The treatment of raw manure will require additional time, possibly creating a need to store manure. The storage of partially processed manure may lead to impacts to surface and groundwater; however, best management practices can reduce the potential for these impacts. The treatment process will require additional inputs in the form of energy, transportation, and money relative to the use of raw manure.

If farmers switch to treated manure and the nitrogen availability of the treated manures is unknown or difficult to predict, then regular testing would be required to allow farmers to properly apply manure to meet agronomic needs and environmental goals (such as those in nutrient management plans). While the current factors may be adequate for general estimating of typical manure nitrogen availability, more precise estimates of nitrogen availability based on compositional analyses are needed to guide producers toward economical and environmentally benign application rates when using treated manures (University of Wisconsin-Madison, 2014). With proper management, we would not expect adverse impact to soil health to occur.

The improper use of chemical fertilizers may have an adverse impact on surface and groundwater; however, proper nutrient management, e.g., proper storage, nutrient management plans, and careful selection of application methods will limit any adverse impact so as not to be significant. As long as chemical fertilizers are used properly, water quality would be expected to return to ambient conditions.

Chemical fertilizers lack the organic matter that manure otherwise provides, and therefore may not bolster soils. Therefore, the use of additional chemical fertilizers to treat fields where raw manure was previously utilized could cause moderate, but not significant, adverse environmental impacts to soils. The degradation of soil quality from using chemical fertilizers may have long-term adverse impacts, which may be reversible through the application of organic matter to the soil. The proper application of nutrients and organic matter would result in no significant impacts to soil function and the soil's ability to filter nutrients, water, and pathogens properly. These impacts may also be reversible by switching to practices such as green manuring. The production and transport of chemical fertilizers may have an adverse impact on energy use and air quality, but not to a significant degree because the resource use is not expected to change substantially as compared to current baseline conditions and the impacts to public health from air emissions would not rise to a significant impact at a regional or national level given the very small number of farms that potentially may make such a management decision.

Changing the application method to prevent the contact of raw manure with a covered produce crop during application will potentially require the acquisition of additional equipment. This would

require the outlay of funds for the purchase of new equipment and its ongoing maintenance. However, we do not expect a loss of income or employment to result at a significant level on a regional or national level due to the small number of farms potentially affected.

If growers choose to switch to growing a non-covered crop, regional produce commodity prices may increase, resulting from a decrease in produce grown in any particular region; however, we expect that demand for a certain produce commodity would eventually be met by other growers in the region, growers in other regions (commodity and environment specific), or international suppliers.

Compared to Alternative I, this alternative is expected to have slightly greater, but not significant, environmental impacts.

4.4 Subpart F / Treated: Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste - Treated Proposed §112.56(a)(4)(i)

FDA's rationale for proposing Subpart F

The role that biological soil amendments play in contributing to pathogen presence on produce is discussed in Chapter 4.3. Proposed Subpart F establishes standards directed to treated and untreated BSAs of animal origin and human waste. These standards include requirements applicable for determining the status of a BSA of animal origin; procedures for handling, conveying, and storing BSAs of animal origin; provisions regarding the use of human waste in growing covered produce; acceptable treatment processes for BSAs of animal origin applied in the growing of covered produce; microbial standards applicable to treatment processes; application requirements and minimum application intervals; requirements specific to agricultural teas; and records requirements (21 CFR Part 112).

This set of management decisions and alternatives applies to treated BSAs of animal origin. Many of the facts and considerations discussed in Chapter 4.3 also apply to these standards. The primary difference is that a larger percentage of farms using treated BSAs of animal origin would potentially be impacted by these standards. As discussed in Chapter 2.1, subpart F (Table 2.1-3), approximately 3,618 covered farms use treated manure.[23] This equates to approximately 10.2 percent of covered farms that use treated BSAs of animal origin.

Agencies are directed to devote the "alternatives" section of an EIS to describing and comparing the alternatives (CEQ 40 Questions, or CEQ, 1981). Under 40 CFR 1502.2, the EIS must be kept concise and no longer than necessary. For these reasons, discussions from Chapter 4.3 that apply to the management decisions considered reasonably foreseeable under this subpart are not repeated below.

[23] This number is derived from adding the number of livestock and produce farms that use treated manure (2,306) to the number of organic produce farms reporting using green manure or BSAs of animal origin (588 farms minus 109 farms using untreated manure = 479 farms), and other farms (1,021 minus 188 farms using untreated manure = 833 farms). Note that the total of these 3,618 covered farms may be using treated manure or green manure. These data cannot be differentiated.

Management Decisions

As discussed under Chapters 4.1 and 4.2, FDA, in coordination with USDA, identified the following actions or mechanisms that a farmer may take in order to either come into compliance with the requirements, or to avoid compliance; these include using BSAs of non-animal origin, using chemical fertilizers, complying with the requisite waiting period (applies specifically to each alternative), and changing the application method.

While all reasonably foreseeable alternatives have been identified, FDA is aware that some management decisions will likely be preferable to covered farms. Alternative I would establish requirements that are substantially similar to the baseline conditions. Therefore, the most likely management decision is that farmers will elect to comply with the proposed provision § 112.56(a)(4)(i), which specifies a 0 day waiting period.

General background on resources related to the proposed provision

Much of the baseline information that is presented under this provision refers back to data presented in Chapters 3.4, 4.1 (the No Action alternative), and 4.2. This section summarizes the relevant baseline data needed to assess the potential environmental impacts for Subpart F, proposed §112.56(a)(4)(i).

Water Resources- The prevalence of irrigated acres where treated BSAs of animal origin are applied is expected to be similar to the percentages stated below (under Waste Generation, Disposal, and Resource Use) (i.e., a small portion of the overall acreage of (irrigated) covered crops can be expected to have BSAs of animal origin applied), but a majority of those farms would be expected to already use treated manure instead of untreated. Furthermore, an even larger percentage of produce growers use elemental fertilizers instead of BSAs of animal origin. Careful calculation of nutrient application rates, and judicious application methods and timing can reduce the potential for surface and groundwater pollution on irrigated land. The chief concern with composted manure (compared with untreated manure and fertilizer) is the amplification of phosphorus and potassium in complex forms that require extended time for plant uptake, therefore causing greater potential for eroded material from land where compost is applied to cause eutrophication of surface waters. Where operators employ conservation tillage and other practices (e.g., grass waterways, strip cropping, etc.), this concern is reduced. But if conservation measures are removed (as a response to growers creating unvegetated buffer areas for monitoring wildlife intrusion), then compost as a soil amendment has the potential to have an increased effect on surface water.

Biological and Ecological Resources- Composting is known to reduce the prevalence of weed seeds relative to raw manure, which could reduce the amounts of herbicide inputs needed in growing areas. Otherwise, there is little relationship between most forms of terrestrial wildlife on farm crop fields and the application of any sort of soil amendment. As mentioned above under water resources, there is some concern in the absence of conservation measures that compost and chemical fertilizers can upset the balance of limiting nutrients in aquatic systems, leading to biogeochemical oxygen demand and eutrophication (“dead zones”) where the problem is prevalent.

Soils- Use of treated manure as a soil amendment (compared to untreated manure) concentrates the amount of nutrients; thus, less land is required for manure application. Composting or digesting manure also reduces manure mass (removes water for example and nitrogen compounds in the form of ammonia off-gassing) and therefore results in less material to transport. The amount of treated BSAs of animal origin needed for production is dependent on the nutrient requirement of the crop and time when the nutrient is needed. Benefits of composted material include (1) improved consistency, (2) lower prevalence of weed seeds, (3) lower loss of nutrients if incorporated immediately, and (4) slower decomposition relative to raw manure, resulting in slower nitrogen release in the soil. Thus, composted manure is one of the best soil building materials (along with green manure cover crops).

Waste Generation, Disposal, and Resource Use- An estimated 4,438 covered-produce-growing farms (12.5% of all covered farms in total) use BSAs of animal origin. A small majority of BSAs of animal origin are generated either on the same farm where they are applied for fertilizing fresh produce, or on a neighboring farm. A large percentage (roughly 47%) of manure products are supplied by commercial manure brokers. Some marketing agreements and USDA Organic programs have definitions of what is considered treatment (composting) that includes aeration to promote decomposition and thermal reduction of pathogens.

FDA's analysts have estimated that 3,618 covered produce farms use composted manures; by comparison, the number using untreated manure is 821 covered farms (FDA, 2013b). These trends are presented in greater detail in Section 3.4. Given that only a relatively small number (2.3 percent of covered farms or 1.56 percent of covered produce acres) currently use untreated BSAs of animal origin, those farms represent the maximum percent of industry that could be expected to change to treated BSAs of animal origin under this provision. Presently, there are no suggested application to harvest intervals for treated BSAs of animal origin.

Air Quality and Greenhouse Gases- Chapter 3.5 has maps that illustrate areas of air quality concerns, which do include regions where produce is grown in conjunction with areas where livestock and poultry are raised (e.g., central and southern California and central Florida). Potential effects to air quality and greenhouse gases due to the use of treated BSAs of animal origin occur when composting or digesting occur and release ammonia and particulate matter (see Section 3.5). In some states, where the implementation plans indicate a requirement for it, major CAFOs and large composting facilities require stationary source air quality permits, monitoring, and abatement, although there is not a nationwide requirement for all such facilities to be regulated. Presently (see Section 3.4), more produce growers are using composted manure than are using untreated manure, which is contrary to the total for all agricultural crops (where untreated manure exceeds compost application in terms of percentages).

Socioeconomics and Environmental Justice- Impacts that are associated with meeting the requirements for standards directed to treated BSAs of animal origin could stem from economic costs to comply with the provision, if finalized. Currently, organic farms and dual-purpose farms can manage composted BSAs of animal origin efficiently and effectively in compliance with federal, state, and local laws and regulations. Dual-purpose farms can also apply untreated or aged manure according to their prescribed state-approved nutrient management plan (if any). The exceptions to this are states with marketing agreement requirements that include several major

growing areas (California, Florida, and Arizona) and several major commodities (e.g., leafy greens and tomatoes), where there are currently limitations on application of BSAs of animal origin. Changes anticipated due to possible application to harvest interval restrictions and changes in application methods would include potential for increased costs (storage/treatment or alternative uses for volumes of animal waste, replacement soil amendments, new equipment) and affiliated socioeconomic effects. FDA has proposed and plans to finalize a rule with multiple provisions aimed at a variety of potential routes of contamination of produce for human consumption. The economic cost of an individual provision and environmental impacts that result from a management decision may not be sufficient to result in changes that could impact employment or result in loss of income. Therefore, socioeconomic impacts, will be addressed in aggregate under Chapter 4.7.

Human Health and Safety- Present practices allow for application of treated BSAs of animal origin up until the date of harvest, although such a practice would not be effective at maximizing plant uptake of the nutrients. This situation presents concerns that pathogens could enter the produce through cultured soils contacting the plant or produce, or through direct contact. Also, without hygiene standards, BSAs of animal origin can be transferred to fruit and vegetables if the BSAs of animal origin are present on the soil surface (unincorporated) during harvest operations, as shown on Figure 3.8-1 (Conceptual Site Model / Transport of Pathogen Microbes).

4.4.1 Alternatives Analysis

This section provides a comparison of alternatives that FDA considered under Subpart F/ Treated BSAs of Animal Origin, and relates the potential environmental impacts from a grower that may select a particular management decision, as discussed at the beginning of this section.

Any of these alternatives is expected to have a significant beneficial impact on human health and safety.

Alternative I.
As proposed, Minimum application interval of 0 days
This is similar to the current baseline conditions. No impacts would be associated with this alternative and corresponding management decisions. The use of chemical fertilizers in place of treated BSAs of animal origin as a nutrient source is unlikely to occur under this alternative because the alternative does not restrict the timing of the use of BSA, only the ability for the BSA to contact covered produce.

Alternative II.
Minimum application interval of 45 days
With the exception of the short season crops listed in Table 3.4-6 with growing to harvest cycles of 45 days or less, most crops have a growing cycle of about three to four months. Therefore, for most crops an application interval of 45 days would not require any changes in the soil amendment type in order to comply with the requisite waiting period. Because this alternative is largely representative of the existing condition, no significant impacts would be associated with this alternative and corresponding management decisions.

Alternative III.
Minimum application interval of 90 days
As discussed under Alternative II, most crops have a growing cycle of about three to four months. Therefore, an application interval of 90 days would not require any changes in the soil amendment type in order to comply with the requisite waiting period. No significant impacts would be associated with this alternative and corresponding management decisions.

4.5 Subpart I / Grazing: Standards Directed to Domesticated and Wild Animals Proposed §112.82(a) Grazing

FDA's rationale for proposing Subpart I
Feces from warm-blooded mammals and birds is a major source of many pathogens that may affect the safety of produce (Francis et al., 1999). Animals are a likely source of contamination of produce (e.g., lettuce, peas, spinach) with human pathogens, and have been identified as a likely cause of illness (Campbell et al., 2001; FAO and WHO, 2008; FDA, 1998; FDA, 2011b; Jamieson et al., 2002). Many species of domestic and wild animals are potential carriers of human pathogens, with both the incidence and concentration of human pathogens varying widely depending upon the animal species (Enache et al., 2011; Franz and van Bruggen, 2008; Leifert et al., 2008; Mazzotta, 2001; NACMCF, 2011; Renter and Sargeant, 2002).

The number and type of pathogens detected in animal feces varies with the animal species. For example, the predominant source of pathogenic *E. coli* O157:H7 from animal feces is cattle, and the predominant source of *Salmonella* spp. from animal feces is poultry (Cramer, 2006; McSwane et al., 1998; WHO, 2006). Cattle are also well-known carriers of different types of pathogens, including strains of *Salmonella enterica, C. jejuni* and other (non-O157:H7) pathogenic *E. coli* (Goulet et al., 2012; NASPHV, 2011; Todd et al., 2007). Beyond cattle and poultry, other domesticated animals such as sheep, goats, and swine are also common carriers of pathogenic microorganisms (Sadowsky and Whitman, 2011).

Domesticated animals (Enache et al., 2011; Renter and Sargeant, 2002) and pests (e.g., rats (Nielsen et al., 2004)) are generally more likely to harbor zoonotic pathogens than are wild animals, due to their closer proximity to and interaction with humans. As wild animals interact more with humans or domesticated animals, they are more likely to become carriers of human pathogens (Nielsen et al., 2004).

As proposed, subpart I provides science-based minimum standards that are directed to domesticated and wild animals and are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FFDCA.

This set of alternatives applies to grazing of domesticated animals. Alternatives directed at wild animals are discussed in Chapter 4.6.

Management decisions

The environmental impacts of standards directed at domesticated animals are the result of the management decisions a covered farm makes in order to comply with the standard. FDA has chosen to take a non-prescriptive approach when establishing the standards in subpart I to allow for, and encourage, scientific advancement in the measures available to comply with the proposed rule.

As discussed in Chapters 4.1 and 4.2, FDA, in coordination with USDA, identified the reasonably foreseeable actions, or management decisions, that businesses potentially affected by any final rule might take in order to come into compliance with alternatives considered under a potentially significant provision. Under Subpart I/Grazing, FDA and USDA identified the following actions or management decisions that a farmer may take once a rule is finalized: fencing or other measures to exclude domesticated animals and observing an adequate waiting period after grazing and prior to harvest. For purposes of this EIS, we have analyzed both of these identified management decisions. We also expect that farmers will carefully consider any management decision to exclude animals (such as through fencing) in light of our proposed provision § 112.84.

General background on resources related to the proposed provision

Much of the baseline information that is presented under this provision refers back to data presented in the No Action Alternative (Chapter 4.1). This section summarizes the relevant baseline data needed to assess the potential environmental impacts for Subpart I, proposed §112.82(a), which establishes the standard related to grazing of domesticated animals.

There are approximately 2,829 dual- and multi-purpose farming operations (raising livestock or poultry and growing produce, inclusive of covered and not-covered or otherwise exempt produce) (USDA NASS, 2014a). The available data are not sufficiently robust to determine which of these dual- and multi-purpose farm operations grow covered produce. An estimated 35,503 farms would be covered by the PS PR (FDA, 2014b). The standard in §112.82(a) would apply to the subset of these operations that grow covered produce, which is between 1.5 and 8 percent of covered farms, with the low end representing the average percent of dual- or multi-purpose farms raising livestock or poultry and growing produce, and the high end assuming all such dual purpose farms are covered by the PS PR.[24] Although there are no reliable estimates to provide precise numbers of farms that would be affected by this standard, we know the following:

- Only a small subset of these farms ostensibly employ either the practice of grazing in produce fields, and those that do may use the area as forage after the growing season, or between rows for tree crops;
- Relatively few farms use poultry as pest control; and,

[24] Given that only approximately 2,829 dual- or multi-purpose farms raise livestock or poultry, and grow produce (and some smaller subset of this number grows covered produce), the overall regional and nationwide potential environmental impacts from grazing operations relative to this rule is minimal. Of the 189,637 farms that grow produce (FDA, 2013b), 2,829 farms represent 1.5 percent of all produce farms. Even if all of the 2,829 dual- or multi-purpose farms are assumed to grow covered produce, it would still represent less than 8% of the 35,503 farms covered by the rule.

- Very few farms in the 21st Century use working animals in their fields, and these farms are concentrated in certain communities with Old Order populations (some Mennonite and most Amish farmers). Therefore, an equally small subset of the 2,829 farms covered produce / animal raising dual or multi-purpose facilities employ working animals.

The potential likelihood of animals to act as vectors of human pathogens is determined by several factors, including, but not limited to, the type of commodity (as discussed above), and the species of the animal and its association with human or domesticated animal activity or waste (FDA, 2013c). A suitable time period based on these and other relevant factors must be established for the purpose of reducing, via die-off, pathogen levels in the excreta that may be transferred from animals to covered produce. For the purposes of this EIS, we included two waiting periods that provide a sufficiently wide range for the evaluation of potential environmental impacts: (1) 9 months, which aligns with FDA's 2013 proposed application interval for use of untreated manure, and (2) 90/120 days, which is in accordance with the supplemental proposed rule (FDA, 2014b), where FDA eliminated the 9-month proposal and, instead, indicated that we do not intend to take exception to the USDA organic regulation standard for the application of untreated manure (90/120 days, see Chapter 2.1) at this time.

Water Resources- Farming operations that may be relevant to the provision would include CAFOs that also grow covered produce. Such facilities are sometimes required to comply with the requirements of a NPDES permit (Chapter 3.4.1 and 3.4.2); however, these permits would be applicable to the management of waste and not to the farm field. State nutrient management plans do not cover the management of grazing livestock on crop fields.

In general, domesticated animals, whether they are allowed to graze in covered fields, are removed from fields for an adequate or specified waiting period, or are fully excluded from fields growing covered produce, would be expected to result in localized soil compaction and thus, increased runoff of nutrients and contaminants into receiving waters, and contributing to (non-point source pollutants) to already poor water quality conditions.

The potential impact to water resources caused by excluding domesticated animals from covered produce, whether for a short or long period of time, would be tied to the fact that animal wastes may be concentrated over smaller areas (pastures or other confined areas), which could lead to somewhat greater concentrations of pathogens reaching the water table as well as an increase in direct runoff (from increased soil compaction) to the surface water. For those covered farms that also include livestock operations (to which this would mostly apply), it is important to distinguish that fences to manage livestock are likely already in place and that the farmer would not likely be building new fencing (see Chapter 2.1 Subpart I, and amended §112.84). The most common grazing activities would occur in dedicated pasture land where perennial grasses grow. We do not believe such impacts to be significant because livestock management does not occur in produce fields, as livestock, if allowed to graze in produce fields would consume much of the commodity.

Since by-and-large, the animals are not used as a primary source to amend the farm field (such as by providing untreated BSAs of animal origin in accordance with subpart F), the amount of animal waste under this provision would be far less in volume than a typical CAFO. Since it is likely that dilution would occur at the point of groundwater recharge (Chapter 3.1.3.5), any adverse

environmental impacts are expected to be minor and short-term as water quality would recover to ambient conditions relatively quickly.

Fowl such as geese and chickens are sometimes used to graze for insects or remove weeds in fields in lieu of using commercial pesticides. Restricting access to livestock (i.e., poultry) that forage the insects inhabiting the farm field may require the increased use of insecticides/pesticides. Insecticides/pesticides are known contaminants in surface and groundwaters throughout the U.S. (see Chapter 3.1.3.5 and 3.1.3.9 Tables 3.1-2, 3.1-4, 3.1-5, and 3.1-7) and are often readily available for transport to surface and groundwater systems (see Chapter 3.1.3.10).

Given that relatively few farms use poultry as pest control in areas where covered crops are grown (estimated between 1.5 and 8 percent of all covered farms), and given that foraging for insects is not expected to be a major food source for domestic fowl, any corresponding switch to using insecticide/pesticide would be limited and is not anticipated to substantially contribute to degradation of water quality conditions at a regional or national level. Therefore, any adverse environmental impacts to water quality from the increased use of chemicals are expected to not be significant. Moreover, as discussed in Chapters 4.1 and 4.2, pesticides contribute to the degradation of water quality conditions. However, when applied in accordance with their labeling requirements, which would be a reasonably foreseeable use, water quality conditions would be expected to recover to ambient conditions.

Biological and Ecological Resources- As discussed in Chapter 3.2.3, agricultural operations are not natural ecosystems (i.e., they are intensively manipulated for the benefit of humans); however, they do provide habitat and other life requisites for many species of plants and animals. As discussed in soils, below, grazing operations often affect the quality of soils on farms in various ways that may have indirect effects on vegetation, aquatic and terrestrial wildlife, and wetlands. Excluding domesticated animals from fields where produce is grown means that other land would need to be used for grazing, or other animal food sources must be used. Any activities that may have impacts to wetlands must first go through a permitting process irrespective of whether the land is private or public (see Chapter 3.2.1). This process often requires the approval of a federal agency such as the Corps of Engineers in concert with state approval. As part of the permitting process, if there is a loss of wetlands expected beyond the State's individual thresholds (each state will have different requirements), then mitigation is often required. In addition, FDA has proposed a new provision, § 112.84, that explicitly states that part 112 does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. FDA does not believe that these types of actions are needed because the grazing typically occurs in dedicated pasture land, and grazing where covered produce is grown does not generally occur during the growing season.

Fencing is the most obvious measure to exclude domesticated animals from crops, whether for a short or long period of time. Because clearing of land would not be required by the proposed rule, if finalized, and because such farms are already likely to have fencing in place to confine animals in general and/or to confine animals from areas where crops are grown, any environmental impacts to vegetation, wildlife, and wetlands are not expected to be significant based on the potentially few

farming operations that decide to fence any particular field or livestock. In terms of fencing, FDA is considering potential impacts on the following components:

Vegetation
Herbaceous species would incur impacts due to the swath of land that would be cleared to allow for fencing. Any impact to vegetation is expected to be minimal, as farmers would likely maintain the exclusion corridors that may already exist surrounding the farmland.

Wildlife
The heightened use of insecticides would generate an escalated level of eco-toxicity to the surrounding habitat, which in-turn may impact target insect species as well as avian and aquatic or amphibious species.

Pesticides receive approval under the FIFRA and its implementing regulations (e.g., registration and labeling requirements found in 40 CFR Parts 152 and 156). EPA-registered products regulated under FIFRA are evaluated to determine potential environmental effects specific to their use and, in order to be registered for use, must be found to not generally cause unreasonable adverse effects on the environment so long as the products are used in accordance with their labeling requirements. The FIFRA-related requirements should help to avoid unreasonable adverse effects to the ecosystem (from the product registration process in relation to specific product testing and handling).

Given the low occurrence of anticipated increases in insecticide/pesticide use (between 1.5 and 8 percent of covered farms nationwide) direct and indirect impacts to wildlife receptors are not expected to rise to a significant impact at a regional or national level.

Given the expected low occurrence of decisions to fence farm land, any impacts are expected to be long-term (the exclusion measure being a semi-permanent structure) and not significant. Additionally, reduced access to forage and cover due to the fencing or other exclusion measures may disrupt the existing wildlife corridors of transient terrestrial animal species, but few such disruptions are anticipated because fencing could be ineffective to exclude wildlife from farm fields. The rate of any such disruption would be expected to be lower than the number of facilities that would need to add fences, as these corridors are not found on every farm. Any disruption is not expected to be significant. Furthermore, if the insecticides are used in accordance with labeling requirements, which would be reasonably foreseeable, even any minimal environmental impacts to water quality should be effectively reduced to a level that is not significant regionally or nationally because the effects of these chemicals are not persistent (see Chapter 3.1.3.10).

Wetlands
Potential increases of toxicity to water and wetlands due to the somewhat heightened level of insecticides may result in adverse environmental impacts to aquatic species. We would not expect the potential adverse effects to aquatic species and wetlands to be significant if the insecticides are used in accordance with their labeling requirements. Wetland vegetation and function, and the effects to aquatic species that may be impacted by pesticide treatments are not considered permanent impacts because the effects of these chemicals are not persistent. EPA, in cooperation with states, carefully regulates these chemicals to ensure they do not pose an unreasonable risk to

human health or the environment. EPA requires manufacturers to conduct extensive testing in order to identify any potential risks, and the agency carefully reviews these data provided by manufacturers before the product may be registered for use. Therefore, as long as users apply insecticides in accordance with the EPA and manufacturers requirements, EPA does not anticipate long-term adverse effects associated with these products (see Chapter 4.1 and 4.2).

Any impacts that may result in a removal of wetlands would most likely require a permit, subject to permitting by the U.S. Army Corps of Engineers and the state where the wetlands may be impacted. Permit provisions often require mitigation in accordance with state requirements, and therefore, these federal, state and local permits would limit the overall impact to state wetland resources and to the species that habituate them.

Soils- Chapter 3.3.3.7 provides a discussion relative to soils and grazing of domesticated animals. Livestock grazing in fields where covered produce is grown affects the structure, composition, fertility, chemistry and function of soil in ways that compromise both short and long-term productivity. Grazing changes soil structure by increasing soil compaction and by increasing runoff of nutrients (e.g., nitrogen related compounds including fertilizers) (Roberson, 1996). Such impacts are described for primarily bovine operations. Therefore, any environmental impacts on soils associated with a change in practice as a result of the proposed standard, such that poultry or other domesticated animals are not used, are not expected to be significant.

In most cases, covered dual- or multi-purpose operations already have fields that are dedicated pasturelands and would not, under normal conditions, be rotated in for crop land. Any impacts to soils in these areas are most likely already occurring, and therefore, no significant impacts from grazing are expected on soils under any management decision or alternative as a result of the PS PR, if finalized.

Waste Generation, Disposal, and Resource Use- Most grazing, and associated waste generation, occurs in the pens and loafing areas where animals are confined. Such grazing presents little difference in terms of nutritive values for produce-growing areas, with minor added efforts for collection and treatment.

Exclusion of grazing animals on a temporary or permanent basis would restrict animals to other pastures for extended periods and/or restrict them to confined feedlots. The effect of such exclusion could be slightly higher volumes of manure accumulations during the times when animals would otherwise graze, and is not expected to result in any difficulties in storing, using, or otherwise disposing of the accumulated animal waste. Therefore, no significant impacts are expected at a regional or national level.

Air Quality and Greenhouse Gases- Although the production of methane (a greenhouse gas) would occur as part of grazing, such impacts with respect to covered crops are already occurring and are not anticipated to change as a result of the proposed grazing requirements; therefore, no environmental impacts from the proposed requirements would be caused by the PS PR, if finalized.

Adding a permanent structure or other measures to exclude domesticated livestock including cattle and fowl, either for a short or long period of time, would have no impact to Air Quality and GHGs

on a regional or national scale as there would be no foreseeable measureable change to the air quality environment by adopting this mechanism to comply with the standard.

There may be minimal air quality impacts associated with some farms depending on the particular action taken to exclude animals from covered produce crop areas. These impacts could include particulate matter emissions from switching to chemical pesticides, and methane and PM emissions from manure storage in concentrated areas (which, as explained above, is not a likely scenario). The quantities at which air emissions could be generated from these activities are very low. Regions where covered farms are concentrated relative to existing poor air quality conditions will experience no measureable change in air quality conditions because while some farms may switch to chemical pesticides, and while methane and PM emissions occur from increased manure storage, the number of covered farms for which these changes in current practices is anticipated is extremely small. Any environmental impacts are not expected to be readily detectable, and therefore, would not be significant. Regions where covered farms are concentrated, where such impacts may occur, include regions C, D, U, and B (see Chapter 3.5.3 Figures 3.5-3, 3.5-4, and 3.5-7).

Socioeconomics and Environmental Justice- Impacts that are associated with meeting the requirements for the grazing standards directed to domesticated and wild animals could stem from economic costs to comply with the final provision. The estimated costs associated with finalizing the rule for this provision are $32.30 million annually for all farms, nationwide. These costs cover both §§ 112.82(a) and 112.83(b) and include developing a monitoring plan and monitoring fields for animal intrusion at various times of year relevant to harvest, and the costs associated with monitoring working animals when in covered fields (FDA, 2014b). FDA has proposed and plans to finalize a rule with multiple provisions aimed at a variety of potential routes of contamination of produce for human consumption. The economic cost of an individual provision, and environmental impacts that result from a management decision may not be sufficient to result in changes that could impact employment or loss of income. Therefore, socioeconomic and environmental justice issues will be addressed in aggregate under Chapter 4.7.

Human Health and Safety- Domesticated and wild animals present a likely contamination pathway for produce (FDA, 2013b and 2013c, see also Chapter 2.1 subpart I). In general terms, domesticated animals in growing areas present some hazards from fecal contamination in the instances where domesticated animals are permitted to graze in fields prior to harvest, or working animals are permitted in fields prior to or during harvest. Requiring the farmer to exclude animals for a short or long period of time would reduce potential pathogenic exposure to consumers. If the farmer takes measures, such as fencing, to exclude domesticated animals from the fields, there would be a moderate beneficial environmental impact on human health and safety. No adverse human health effects would be expected.

4.5.1 Alternatives Analysis

This section provides a comparison of alternatives that FDA considered under Subpart I/Grazing and relates the potential environmental impacts from a grower that may select a particular management decision, as discussed at the beginning of this section.

Any of these alternatives and management decisions are expected to have a moderate beneficial impact on human health and safety.

Alternative I.
As proposed, Adequate waiting period
Given that only approximately 2,829 dual- or multi-purpose farms raise livestock or poultry, and grow produce (and some smaller subset of this number grows covered produce), the overall regional and nationwide potential environmental impacts from grazing operations, in general, is minimal (as discussed at the beginning of this chapter, we estimate the impacts would be relevant to approximately from 1.5 percent to at most 8 percent of the farms covered by the PS PR).

Although some measures to permanently exclude domestic animals from covered produce, such as fencing, would be permanent, most farms are expected to already have these structures available. Of any farms that do not currently have such fencing, any adverse environmental impacts from farms taking a measure to exclude domestic animals from covered produce are not expected to be significant. This is because related impacts to fencing could include clearing a border around the farm field, thereby potentially removing vegetation. Reduced access to forage and cover for wildlife species due to the fencing or other exclusion measures may disrupt the existing wildlife corridors of transient terrestrial animal species, but few such disruptions are anticipated because exclusion measures could be ineffective to prevent wildlife from entering farm fields and because general impacts to wildlife habitat would be limited to the borders of the fields where such exclusion measures may be implemented. The application of chemicals such as herbicides to control vegetation around farm fields, and the application of insecticides/pesticides to control other pests could result in adverse effects to water quality. However, when applied in accordance with their labeling requirements, which would be a reasonably foreseeable use, the impacts are not expected to be significant, and water quality conditions would be expected to recover to ambient conditions. The quantities of air emissions and GHGs related to fencing or other exclusion measures are not expected to result in public health concerns because there would be no measureable change to the air quality environment over existing conditions. In addition, all of these aforementioned impacts take into consideration the very small number of farms potentially affected by this provision where such impacts may occur.

The term “adequate waiting period” is not defined by the PS PR. What can be deemed adequate relative to specific in-farm practices such as crop rotation or seed to harvest intervals would need to be determined at the farm level. The more likely management decision when determining when to remove the animal from the field at some time during the planting-to-harvest interval would be to factor in the crop, and region where the crop is grown to allow for consideration of late growing seasons and other factors. Unlike Alternatives II and III, this alternative provides flexibility for farmers to make the decision on an appropriate time interval, based on the farm’s operation.

As discussed earlier in Chapter 4.5, the most common grazing activities occur in dedicated pasture land where perennial grasses grow. Livestock management does not occur in produce fields, as livestock, if allowed to graze in produce fields would consume much of the commodity. Because we anticipated that such dual-purpose operations already have confined grazing or other areas for livestock, removing the animal from fields where covered produce may be grown, relative to a

planting/harvest interval, is not anticipated to result in adverse impacts beyond baseline conditions to either the produce field or to the field(s) where the animal is confined.

Any measure taken to reduce the hazard from pathogen transport to produce is expected to result in beneficial impacts to human health; however, relative to a permanent exclusionary measure, a management decision to include an adequate waiting period before using a field for growing covered produce may not have the same level of human health benefits (foodborne illnesses prevented) compared to creating a barrier to animal entry and grazing entirely. A notable exception to human health benefits could be the use and handling of chemicals as part of a strategy to exclude domestic animals from farm fields. However, as discussed in Chapter 4.1 and 4.2, the proper use and handling of such chemicals, and adherence to manufacturer's recommendations for using personal protective equipment, are reasonably foreseeable uses of these products and we would not expect significant adverse effects to human health from these uses.

Alternative II.
Waiting period of 9 months
As compared to Alternatives I and III, there are no substantially different impacts that can be estimated at a regional or national level, and, in addition, all alternatives take into consideration the very small number of farms to which this provision would apply.

Alternative III.
Waiting period of 90/120 days
As compared to Alternatives I and II, there are no substantially different impacts that can be estimated at a regional or national level, and, in addition, all alternatives take into consideration the very small number of farms to which this provision would apply.

4.6 Subpart I / Animal Intrusion: Standards Directed to Domesticated and Wild Animals Proposed § 112.83(b) Animal Intrusion

FDA's rationale for proposing Subpart I
As discussed in Chapter 4.5, animals are a likely source of contamination of produce (e.g., lettuce, peas, spinach) with human pathogens, and have been identified as a likely cause of illness (Campbell et al., 2001; FAO and WHO, 2010; FDA, 1998; FDA, 2011b; Jamieson et al., 2002). Wild animals, including pests, can also act as reservoirs of human pathogens (Fischer et al., 2001; Jay et al., 2007). Pathogenic *E. coli* have been isolated from deer, feral swine, pigeons and seagulls (Fischer et al., 2001; Jay et al., 2007; Nielsen et al., 2004), and Dunn and colleagues report that the prevalence of *E. coli* O157:H7 infection in white-tailed deer ranges from a level that is undetected to 2.4 percent (Dunn et al., 2004).

As proposed, subpart I provides science-based minimum standards that are directed to domesticated and wild animals and are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FFDCA.

This set of alternatives applies to animal intrusion.

Management decisions
The environmental impacts of standards directed at domesticated wild animals are the result of the management decisions a covered farm makes in order to comply with the standard. FDA has chosen to take a non-prescriptive approach when establishing the standards in subpart I to allow for, and encourage, scientific advancement in the measures available to comply with the proposed rule.

As discussed in Chapters 4.1 and 4.2, FDA, in coordination with USDA, identified the reasonably foreseeable actions, or management decisions, that businesses potentially affected by any final rule might take in order to come into compliance with the alternatives under consideration for inclusion in the final rule. Under Subpart I/Animal Intrusion, FDA and USDA identified the following actions or management decisions that a farmer may take with respect to this subpart if the rule were finalized: (1) to avoid harvesting the field or part of the field or (2) to take measures, such as fencing, to exclude wildlife. For purposes of this EIS, we have analyzed both of these identified management decisions, although we expect that farmers will carefully consider any management decision to exclude wildlife (such as through fencing) in light of proposed provision § 112.84.

General background on resources related to the proposed provision
Much of the baseline information that is presented under this provision refers back to data presented in Chapters 3.2, 4.1 (No Action alternative), and 4.5. This section summarizes the current conditions needed to assess the potential environmental impacts for Subpart I, proposed § 112.83(b).

Relative to the PS PR, farms that may be affected include all potentially covered farms nationwide (35,503 farms), and their 4,473,575 associated acres (Chapter 2.1 and FDA, 2014b).

Proposed subpart I would apply when under the circumstances there is a reasonable probability that wildlife will contaminate covered produce. In such circumstances, proposed subpart I would require monitoring of those areas that are used for a covered activity for evidence of animal intrusion immediately prior to harvest and as needed during the growing season, and if animal intrusion, as made evident by observation of significant quantities of animals, animal excreta or crop destruction via grazing, occurs, the farm would be required to evaluate whether the covered produce can be harvested safely (proposed §§ 112.81 and 112.83). Monitoring wildlife activity at or around covered produce is key to identifying potential hazards.

Water Resources- Wildlife exclusion is anticipated to have no impact on water used for covered produce. Any potential land clearing that involves the application of chemicals to kill herbaceous species, or any type of rodenticide that may be applied adjacent to the farm field, if used in accordance with labeling requirements, would be anticipated to have minimal, but no significant adverse environmental impacts to water quality. This is because water quality conditions would be expected to recover to ambient conditions. In addition, as discussed in Chapter 4.1 and 4.2, when such chemicals are applied in accordance with their labeling requirements, which would be

a reasonably foreseeable use, the impacts are not expected to result in significant impacts to the environment.

Since the majority of the water use would have already occurred during the growing season, not harvesting a field or part of a field would also have no anticipated impacts on water resources, as no additional water use would be needed, nor would this process involve any additional pesticide use.

Biological and Ecological Resources- FDA received various comments that expressed the concern that the 2013 proposed rule, if finalized as proposed, would adversely affect wildlife. These comments were reiterated in response to the supplemental proposed rule and the Draft EIS. Comments noted that animal habitat, habitat connectivity, and wildlife populations would be at risk if our proposed provisions related to animal intrusion are perceived by produce growers to mean that less habitat and/or more fencing in the production environment is a necessary management strategy (79 Fed. Reg. 58434 at 58463-58464). With respect to wildlife generally, Part 112 would not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. FDA addresses the scope of the EIS, with regard to threatened and endangered species, at the beginning of Chapter 4.

There are available co-management measures which allow growers to direct wildlife away from fields while still providing adequate habitat. Best management practices associated with certain co-management measures may help to minimize any potential adverse impacts to wildlife, generally, or the environment as they allow growers to, for example, direct wildlife away from fields while still providing adequate habitat.

Hunting, trapping, and animal poisoning are other methods that are sometimes used to manage wildlife species at or adjacent to farm fields. Hunting and trapping are often accomplished in accordance with state or county permit requirements and in accordance with state wildlife regulations, which factor in species population levels before determining the number of licenses/permits that can be issued without adversely impacting the species survivability. Individual states have the responsibility for regulating the use of wildlife native to that state (USFWS, 2000). For example, deer damage permits may be available to farmers that have experienced crop damage as a result of deer entering their production fields. These permits allow for the shooting of a specified number of deer during a certain period, usually outside of the normal hunting season.

Vegetation

Herbaceous species would endure impacts due to the swath of land that would be cleared to allow for fencing. Any impact to vegetation is expected to be minimal, as farmers would likely maintain the exclusion corridors that may already exist surrounding the farmland. However, if all or part of the field is not harvested, a minimal beneficial impact to vegetation whereby the non-harvested crops are left to be tilled back into the soil may occur due to the additional nutrients being added back into the soil.

Wildlife

Any heightened use of herbicides, rodenticides, or other chemicals that may be used to exclude wildlife may adversely affect wildlife that were not meant to be harmed. These effects may be experienced by insect species, as well as avian and amphibious species, and aquatic species found in surface waters adjacent to the where the chemicals are applied. These effects would be limited, as the chemical components would quickly dissipate or decompose. Because these effects are generally considered to be of low toxicity and because the species that may be affected are generally resilient to the effects of the chemicals, the overall anticipated impacts are adverse but not significant. We would expect the chemicals to be used in accordance with their labeling requirements. Moreover, as discussed in Chapters 4.2, the overuse of pesticides may result in damage to soils and to crops, the general cost of these chemicals to apply may make it prohibitive to apply in higher quantities than what is needed to control pests on the farm field, and often such chemicals are applied by certified users and are therefore increase the likelihood that chemicals are applied in accordance with the applicable regulations. EPA, in cooperation with states, carefully regulates these chemicals to ensure they do not pose an unreasonable risk to human health or the environment. EPA requires manufacturers to conduct extensive testing in order to identify any potential risks, and the agency carefully reviews these data provided by manufacturers before the product may be registered for use. We do not anticipate significant adverse effects associated with these products.

Additionally, reduced access to forage and cover due to the fencing or other exclusion measures may disrupt the existing wildlife corridors of transient terrestrial animal species, but few such disruptions are anticipated because fencing may be ineffective to exclude wildlife from farm fields. The rate of any such disruption would be expected to be lower than the number of facilities that would need to add fences as these corridors are not found on every farm. Any disruption, e.g., fencing, is not expected to be significant because general impacts to wildlife habitat would be limited to the borders of the fields where such exclusion measures may be implemented.

If all or part of the field is not harvested, the produce that was unable to be harvested would be accessible for forage and cover for transient species, and there would be a short-term minimal beneficial environmental impact due to the temporary increased availability of food.

Wetlands

Localized use and application of herbicides to maintain monitoring areas or otherwise clear vegetation has the potential to be toxic to wetland plants, which may impact wetland function. If such products are used in accordance with labeling requirements, the anticipated impacts to wetlands adjacent to the farm field may be considered short-term and minimal adverse. This is because EPA, in cooperation with states, carefully regulates these chemicals to ensure they do not pose an unreasonable risk to human health or the environment. EPA requires manufacturers to conduct extensive testing in order to identify any potential risks, and the agency carefully reviews these data provided by manufacturers before the product may be registered for use. Therefore, as long as users apply herbicides (or similar chemicals) in accordance with the EPA and manufacturer requirements, which would be a reasonably foreseeable use (see Chapters 4.1, 4.2 for our rationale regarding the reasonable use of such products), we do not anticipate significant adverse effects associated with these products. Wetland species are resilient and would be expected to recover to the previously existing condition once the chemicals have dissipated or decomposed.

Soils- Overall monitoring for signs of intrusion and determining if the field or part of the field can be harvested could improve the soil since unharvested produce would return nutrients and biomatter, assist in breaking up compaction, prevent erosion, and/or suppress weeds. Minimal beneficial environmental impacts to soils may occur and therefore would not be expected to be significant.

Waste Generation, Disposal, and Resource Use- Wild animal waste is not collected, stored, handled, used, or otherwise disposed of prior to, during, or post-harvest under any circumstances. No impacts on waste generation, disposal or resource use are anticipated as a result of standards directed at animal intrusion.

Air Quality and Greenhouse Gases- There is no direct identified link between air quality and animal intrusion.

Socioeconomics and Environmental Justice- Based on the cost-benefit analysis and consideration of costs in considering this alternative (40 CFR 1502.23), the costs to monitor species, and loss of revenue from unharvested contaminated crops is expected to be low and is not expected to result in loss of employment or income. This is because monitoring is not expected to occur daily (FDA's PRIA (2013b) estimated monitoring to occur three times per production season) and because it is unlikely that a farmer would choose to not harvest a whole field (it is more likely that the farmer would not harvest only that smaller portion of the crop that is contaminated). Because the economic cost of an individual provision and the socioeconomic impacts that result from a management decision may not be sufficient to result in changes that could impact employment or loss of income, the socioeconomic and environmental justice issues will be addressed in aggregate under Chapter 4.7.

Human Health and Safety- Excreta from domesticated animals poses a greater likelihood of contamination of produce than does excreta of wild animals; however, domesticated animals can be expected to be more readily controlled (i.e., kept apart from produce growing, harvesting, and postharvest areas). Excreta from wild animals that rarely associate with human activities poses the least likelihood of contamination of produce.

Wild animals, including pests, can also act as reservoirs of human pathogens (Fischer et al., 2001; Jay et al., 2007). Pathogenic *E. coli* have been isolated from deer, feral swine, pigeons and seagulls (Fischer et al., 2001; Jay et al., 2007; and Nielsen et al., 2004), and the prevalence of *E. coli* O157:H7 infection in white-tailed deer ranges from a level that is undetected to 2.4 percent (Dunn et al., 2004) (FDA, 2013c).

Requiring the farmer to evaluate whether or not covered produce should be harvested based on the likelihood of being contaminated by animal intrusion would reduce potential pathogenic exposure to consumers. If the farmer does not harvest the field or part of the field in order to avoid harvesting contaminated covered produce, there would be a moderate beneficial impact on human health and safety. However, this impact would depend on actually observing the contaminant (feces), which may be relatively easy to miss during monitoring or harvest activities, thereby reducing otherwise the beneficial impacts to one that is minimal.

Measures taken to exclude wildlife may also result in a moderate, but not significant, beneficial impact to human health when considered individually; however, when these impacts are added to the overall aggregate impacts of the rule, as discussed in Chapter 4.7, the corresponding reduction in the potential for pathogens to contaminate covered produce and beneficial impacts on human health would be significant. A notable exception to human health benefits could be the use and handling of chemicals as part of a strategy to exclude domestic animals from farm fields. However, as discussed in Chapter 4.1 and 4.2, the proper use and handling of such chemicals, and adherence to manufacturer's recommendations for using personal protective equipment, are reasonably foreseeable uses of these products and we do not expect significant adverse effects to human health from such uses.

4.6.1 Alternatives Analysis

This section provides a comparison of alternatives that FDA considered under Subpart I/Animal Intrusion, and relates the potential environmental impacts from a grower that may select a particular management decision, as discussed at the beginning of this section.

Any of these alternatives is expected to have a beneficial impact on human health and safety.

Alternative I.
As proposed, Evaluate whether produce can be harvested safely
Under Alternative I, there would be no significant adverse impacts expected with respect to any specific resource component.

Evaluating whether produce can be harvested safely and, as appropriate, not harvesting a field or part of a field that is reasonably believed to be contaminated from wildlife intrusion would have no environmental impacts to water resources, waste generation, disposal, and resource use, and air quality. There may be minimal, non-significant beneficial environmental impacts observed to wildlife species as a result of added short-term cover and forage area from not harvesting part of the field and to soils from nutrients and carbon that would be reincorporated into the soils and lengthened surface cover to maintain or improve soil health.

In terms of reducing pathogens, impacts are expected to be beneficial.

Alternative II.
Measures to exclude wildlife
As compared to Alternative I, environmental impacts would be greater.

Measures to exclude wildlife (including measures to clear land to facilitate monitoring) may involve the use of herbicides, rodenticides, or other materials that may have toxic effects to water resources, biological resources and ecosystems directly adjacent to the farm, and soils. These impacts may be reduced through proper use and handling in accordance with labeling requirements, which would be the reasonably foreseeable use.

The chemical components generally quickly dissipate or decompose, and do not persist in the environment. Therefore, we do not anticipate significant adverse effects from the use of these products. Moreover, measures that may be employed to reduce any potential adverse effects include preparing pest management plans that are discussed earlier in this chapter.

Hunting, trapping, and animal poisoning are other methods that are sometimes used to manage wildlife species at or adjacent to farm fields. Hunting and trapping are often accomplished in accordance with state or county permit requirements and in accordance with state wildlife regulations, which factor in species population levels before determining the number of licenses/permits that can be issued without adversely impacting the species survivability (USFWS, 2000). For example, deer damage permits may be available to farmers that have experienced crop damage as a result of deer entering their production fields. These permits allow for the shooting of a specified number of deer during a certain period, usually outside of the normal hunting season.

Under this Alternative, proposed § 112.84 could also state that Part 112 does not require covered farms to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

In terms of reducing pathogens, impacts are expected to be beneficial.

4.7 Subpart A: General Provisions (Scope of Coverage of the Proposed Rule); includes impacts related to the aggregate effects of each proposed standard assessed together

FDA's rationale for proposing Subpart A

The PS PR proposes to establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce for human consumption, in order to minimize the risk of serious adverse health consequences or death from consumption of contaminated produce. FDA's rationale for establishing these standards is described in detail in Chapter 1.4, with discussions related to the need for potentially significant provisions outlined in Chapters 4.2 through 4.6.

As proposed, subpart A of the proposed regulation contains provisions that establish the scope of, and definitions applicable to, the PS PR, and identifies who would be subject to the requirements of part 112, if finalized. The PS PR would apply to both domestic and imported produce. However, the PS PR would not apply to (1) certain specified produce commodities that are rarely consumed raw, (2) produce that is used for personal or on-farm consumption, (3) produce that is not a raw agricultural commodity, (4) produce that receives commercial processing that adequately reduces the presence of microorganisms (*e.g.,* a ''kill step'') as long as certain documentation is kept, and (5) produce grown on farms that have an average annual value of produce sold during the previous three-year period of $25,000 or less. The PS PR would also provide a qualified exemption and modified requirements for farms that meet certain requirements specified in the regulation.

Management decisions

Unlike with standards directed at specific potential routes of pathogen introduction, proposed § 112.4 in subpart A of the PS PR establishes the value of produce sold above which a farm growing

covered produce would be subject to the provisions of the rule (i.e., covered farms). Covered farms would be required to either comply with the provisions of the rule, including through the use of the management decisions described in Chapters 4.2 through 4.6, or switch to crops that are not covered by the proposed rule.

Complying with the rule would mean that a farmer would have to abide by the provisions of the rule, except where the grower would qualify for certain exclusions from coverage of the rule (such exclusions are discussed briefly above and in more detail in Chapter 2.1). FDA is not evaluating the potential environmental impacts at the local level as part of this EIS; rather, it is focused on regional and national environmental impacts. Potential environmental impacts related to specific qualified exemptions would require an analysis of the very small and small farms that may qualify for certain exemptions and information about such farms on a local level across the country.[25] However, farms that are subject to these exemptions would continue to utilize current practices, so no significant environmental impacts would be associated with those farming practices and the PS PR. There is economic and foodborne-illness-related information available for different farm sizes. FDA considers, below, the relationship between the economic cost-benefit analysis, including information about foodborne illnesses, and the analyses of unquantified environmental impacts from the PS PR to consider the overall impact of the PS PR.

The impacts associated with a decision to switch to crops exempt from regulation under the PS PR, if finalized, would be substantially similar to the decision to cease growing covered produce assessed in Chapter 4.2; therefore, this related analysis that is presented in Chapter 4.2 is not repeated here, and the reader may refer back to that section of Chapter 4.2 for further detail on FDA's thinking of potential environmental impacts. Whether farmers stop growing covered produce is dependent upon many factors, cost being just one. Farmers would consider what other crops they might grow while using the equipment they have in order to avoid purchasing and maintaining new equipment; they might also consider climate and the types of crops available to them in that region, geology and soil characteristics, topography, availability of water, local and regional consumer markets, and much more.

General background on resources related to the proposed provision

The impact analysis in this chapter takes into consideration the aggregate impacts of all provisions in the PS PR, including impacts related to the economic cost and potential socioeconomic impacts from provisions excluded from further analysis in Chapter 2.2 and the impacts identified in Chapters 4.1 through 4.6. The management decisions that farmers may take if they are covered by the proposed rule under proposed subpart A relate directly to the management decisions that farmers may take when considering how best to manage their business with respect to potentially significant provisions of the rule: agricultural water (subpart E), BSAs of animal origin (subpart F), and domesticated and wild animals (subpart I).

For the purpose of this evaluation, the comparison of environmental impacts is accomplished by considering the alternatives that would best fulfill FDA's statutory mission and responsibilities

[25] FDA estimated the number of potentially covered farms that may be eligible for a qualified exemption from the rule. This information is presented in the PRIA (FDA, 2013b). These exemptions apply to farms based on their eligibility as described in proposed § 112.5.

(see Chapter 2.1). For untreated BSAs of animal origin, where FDA has signaled its intent to defer finalization of a standard, the zero days standard proposed in the 2013 proposed rule is used for purposes of this evaluation. Please note that a comparison of potential environmental impacts by alternative for each potentially significant provision is already accomplished in Chapters 4.2 through 4.6.

FDA proposes three main size classifications of businesses in relation to the PS PR. Within the size classifications are businesses that are not subject to the proposed rule, and businesses that are subject to the proposed rule. The size classifications of businesses (farms or farm mixed-type facilities) include not covered (excluded), very small businesses, and small businesses. All other covered farms are considered "large" businesses.[26] These size classifications and associated potential exemptions are discussed in Chapter 2.1 (see also Tables 2.1-7 and 2.1-8).

As discussed in Chapter 2.1, of the 189,637 farms that grow produce, an estimated 18.7 percent, or 35,503, are covered farms (i.e., grow produce that would be covered by the PS PR). Of these 35,503 covered farms, approximately 7,302 would be considered large farms, 4,139 would be small farms, and 24,062 would be very small farms (FDA, 2014b). The geographic locations of covered farms can be found in Figure 1.7-4 in Chapter 1.7. The majority of potentially covered produce is grown in regions B, C, D, L, and U; however, as demonstrated throughout Chapter 4, these and other regions may be impacted by proposed provisions of the PS PR in different and important ways. These differences are summarized as overall potential impacts by potentially significant provision, as presented below.

Subpart E: Standards directed to agricultural water

Table 4-4 presents a summary of potential impacts and comparison of alternatives under subpart E, as discussed in Chapter 4.2.

Table 4-4. Summary and comparison of alternatives under subpart E

Comparison of Alternatives
Alternative I: As Proposed. GM ≤ 126 CFU generic E. coli/100ml and STV ≤ 410 CFU/100ml with added flexibility for microbial die-off and/or removal
• The flexibility in meeting the proposed water quality standard is likely to reduce the need to use chemical treatment of a water source with poor water quality. It is also likely that a farmer might add a post-harvest mechanism to allow for added microbial die-off and/or removal. • Disinfectants may be useful for reducing hazards that may cause foodborne illnesses; however, many of these disinfectants may form harmful byproducts. There is no EPA-registered pesticide that is approved for use for antimicrobial treatment of agricultural water used during the growing of crops. FDA cannot predict what the future actions of EPA, if any, will be with respect to registration of a pesticide to treat agricultural water, much less evaluate the unknown and speculative actions under NEPA. EPA-registered pesticide products are evaluated to determine potential environmental effects and potential impacts to human health specific to their use. We would expect environmental impacts from registered pesticide uses to not be significant considering how they are generally handled and

[26] While the provision specifically discusses "businesses," for the purpose of our evaluation of impacts (and to be consistent with how we address impacts to businesses throughout the EIS) we also refer to businesses as "farms."

applied according to label directions, which would be a reasonably foreseeable use (see Chapters 4.1 and 4.2). When used properly, the adverse effects of such chemicals are not persistent in the environment, and water quality conditions would be expected to return to ambient conditions; wildlife, vegetation, and wetlands would be resilient to the effects of the chemicals at a regional or national level. In addition, a high number of growers in key growing regions, such as California, Arizona, and Florida (Regions C, D, and U), already participate in marketing agreements that have more stringent numeric water quality standards than what FDA has proposed, and are already using water that would be in compliance with the proposed standard. In general, the existence of these marketing agreements, particularly in produce growing regions currently experiencing water impacts, minimizes the severity of potential impacts on resource components associated with a final rule, as the number of farms that may need to alter their current management practices is less than the total number of covered farms.

- It is not likely that a farmer will change the water source or cease growing covered produce because among the regions that are potentially most affected (B, C, D, I, J, and U), many farmers have entered into marketing agreements that are the same as, or operate under more stringent water quality standards than those proposed in the PS PR. In addition, reactions and verbal comments from some industry and trade groups that FDA received on the supplemental proposed rule suggest that the new proposed provisions for microbial die-off and/or removal to achieve the proposed microbial quality standard considerably reduce the perceived need to change water source in order to comply with Alternative I (and similarly Alternatives IV-a, III, and IV-c), compared to Alternative II or IV-b. Any action that may lead to increases in groundwater drawdown would be considered a significant environmental impact. Regions that may be most impacted in terms of potential land subsidence, including any additive effects by switching to groundwater sources, include the regions that already experience the highest groundwater withdrawals; these are regions B, C, D, I, J, and U. Such effects related to groundwater drawdown may further be experienced in the northeastern and northcentral reaches of Mexico, corresponding to groundwater withdrawals from aquifers in regions D, I, and J in the United States.
- Overall, there would be an expected added public health benefit from an estimated 522,083 foodborne illnesses prevented (FDA, 2013b) from the standard itself.
- Air quality emissions would not be expected to result in adverse effects to human health at a regional or national level.

Alternative II: 235 CFU (or MPN) generic E. coli /100 ml single sample or a GM of no more than 126 CFU (or MPN)/100 ml

The adverse environmental impacts and beneficial public health benefits that may apply under Alternative I would also apply under this alternative; however, due to the more stringent requirements for this alternative, the following environmental impacts may occur in addition to those discussed under Alternative I:

- Under this alternative, switching water source is expected to be the preferred management decision. As compared to Alternatives I, IV-a, III, or IV-c, this alternative would not have the added flexibility for microbial die-off and/or removal; therefore, farmers are more likely to decide to switch water sources, particularly away from surface waters to a cleaner source. If the cleanest available source is groundwater, then existing significant adverse conditions (i.e., water drawdown, potential subsidence, and the related continued degradation of water quality) may continue to be exacerbated but to a greater degree than Alternative I, because the water quality requirements would be more stringent under this alternative, and more farms are potentially likely to switch to the groundwater source in numbers that may considerably influence groundwater sources. These impacts are expected to be limited to certain regions and are not expected to be widespread. The regions that may be most affected are B, C, D, I, J, and U. Effects related to groundwater drawdown may further be experienced in the northeastern and northcentral reaches of Mexico, corresponding to groundwater withdrawals from aquifers in regions D, I, and J in the United States. These regions may also experience irreversible effects to soils. Therefore,

these impacts under Alternative II related to lowering the water table, deteriorating water quality, and land subsidence are considered significant adverse.

- Native American Tribes may be disproportionately impacted as groundwater drawdown could have potential environmental impacts including socioeconomic impacts related to access to water on reservations, particularly in regions B and J. Such impacts would be considered significant adverse if there is a reduction in a Tribe's access to water.
- Treating any water source to remove harmful pathogens would have an added public health benefit by reducing the potential for foodborne illnesses.
- There would also be greater potential for the use of chemical treatments to bring water into compliance under this alternative relative to Alternatives I, IV-a, III, or IV-c. Consequently, we would anticipate that this alternative would have more adverse environmental consequences than Alternatives I, IV-a, III, or IV-c. As previously stated, all pesticides must be registered by EPA and must be found to not generally cause unreasonable adverse effects on the environment when properly used. When used properly, the adverse effects of such chemicals are not persistent in the environment, and water quality conditions would be expected to return to ambient conditions; wildlife, vegetation, and wetlands would be resilient to the effects of the chemicals at a regional or national level. However, without the added flexibility for die-off that is afforded under Alternatives I, IV-a, III, or IV-c, regions that potentially require a higher level of chemical treatment include A, B, C, L, R, T, and U. Generally, long-term, sustained treatment of water sources may result in adverse, but not significant impacts to water quality, and may also result in non-significant, adverse long-term effects to biological/ecological resources and air quality from chemical treatments. Even under these circumstances, chemicals are not expected to persist and water quality conditions would be expected to return to ambient conditions; wildlife, vegetation, and wetlands would be resilient to the effects of the chemicals at a regional or national level.
- The risk of adverse impacts to human health relating to the increased use of chemicals would not be expected to be significant and may be limited, considering labeling requirements, as the FIFRA registration process considers risk to human health and establishes handling processes that are appropriate to minimize such risks. The possibility of potential impacts from THMs to be formed may occur in regions that may require the highest treatments (see above). To the extent a future EPA-registered pesticide includes a chemical that results in the formation of THMs, these substances are not expected to be formed at levels that may endanger public health with properly application (see Chapter 4.2). Overall reductions in foodborne illnesses are expected to be comparable under Alternative I, IV-a, III, and IV-c.
- Air quality emissions would not be expected to result in adverse effects to human health at a regional or national level.

Alternative III: As proposed (i.e., Alternative I), with an additional criterion establishing a maximum generic *E. coli* threshold

- Compared to Alternatives I and IV-a, there is a slightly higher likelihood that more farmers may select to chemically treat water sources or switch water sources altogether because there may be circumstances when the pathogen level would exceed the established threshold and when steps allowing for die-off would not be sufficient to be in compliance with the rule. However, the reduced water testing and the less stringent standard means that fewer farms would be expected to make these management decisions as compared to Alternatives II and IV-b.
- The beneficial environmental impacts to health would likely be higher than Alternatives I and IV-a, and lower than Alternatives II and IV-b.
- Similar to what is addressed above, the use of pesticides is found to not generally cause unreasonable adverse effects to the environment, so long as such products are handled in accordance with their labeling requirements (see Chapter 4.2). We would expect adverse impacts to human health related to

handling such substances and treating poor water quality to be not significant, but such future registered uses, if any, are unknown and simply speculative at this time.

- As compared to Alternative I, establishing a maximum threshold for generic E. coli may cause some growers in a region where the water quality is poorest to potentially shift from growing covered produce, but not to the degree that may occur under Alternatives II or IV-b. These potential shifts are minimized by the fact that existing marketing agreements in the most impacted regions already operate with more stringent numeric water quality standards, and also account for more than 80 percent of the produce that would be covered by the rule.

Alternative IV: Alternatives for direct water application method

- Similar to Alternative I, under Alternative IV-a mechanism(s) to account for microbial die-off and/or removal is expected to be the preferred management decision. Due to the added flexibility associated with this alternative, long-term chemical treatment of agricultural water would not be necessary. Therefore, under Alternative IV-a, switching water source and ceasing to grow covered produce are not expected to be preferred management decisions. The impacts under Alternative IV-a would be substantially similar to those identified under Alternative I, and slightly fewer impacts as compared to Alternatives III and IV-c. Environmental impacts are expected to be significantly less than those identified under Alternatives II and IV-b.
- Under Alternative IV-b, there may be a greater potential to switch to a cleaner water source or to treat the water source in order to meet the microbial water quality standard as compared to Alternatives I, IV-a, III, or IV-c. The impact analysis under Alternative IV-b would be substantially similar to those identified under Alternative II; therefore, impacts are expected to be greater under this alternative as compared to Alternatives I, IV-a, III, or IV-c.
- Under Alternative IV-c, there is a somewhat greater potential to switch to a cleaner water source or to treat the water source in order to meet the microbial water quality standard as compared to Alternatives I and IV-a, but less of a potential to select these management decisions as compared to Alternatives II and IV-b. The impact analysis under Alternative IV-c would be substantially similar to those identified under Alternative III, therefore, impacts are expected to be greater under this alternative as compared to Alternatives I and IV-a.

Subpart F: Standards directed to BSAs of Animal Origin and human waste

Table 4-5 presents a summary of potential impacts and comparison of alternatives under subpart F, as discussed in Chapters 4.3 and 4.4.

Table 4-5 Summary and comparison of alternatives under subpart F

Comparison of Alternatives
Untreated BSAs
Alternative I. As Previously Proposed- Decision Deferred. Untreated BSAs of animal origin must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 9 months
• Covered produce growers located in regions A, B, C, D, J, M, L, P, S, U and V are located in proximity to livestock and/or poultry operations, which are a source of available BSAs of animal origin. • Given the long interval between application and harvest, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period. • If farmers switch to treated manure and the nutrient availability of the treated manures is unknown or difficult to predict, then regular testing would be required to allow farmers to properly apply manure to meet agronomic needs and environmental goals. With proper management, no adverse impact to soil health will occur. In addition, treatment will require additional storage time, which presents more opportunity for partially processed manure to impact surface and groundwater; however, adherence to common best management practices may reduce these impacts. If the storage of manure occurs at a facility that operates under an NPDES permit, as long as the facility is managed in accordance with permit requirements, potential adverse impacts are anticipated to further be limited (not all of these farms will have a requirement for NPDES permits). • The production and transport of chemical fertilizers may have an adverse but not significant impact on energy use and air quality because the resource use is not expected to change substantially as compared to current baseline conditions and, therefore, the impacts to public health from air emissions would not rise to a significant impact at a regional or national level (see Chapter 2.1 subpart F, Chapter 3.4, and Chapter 4.3). • Given the small number of farms that use untreated BSAs of animal origin (estimated at 821 covered farms, or 2.3 percent of covered farms nationally) that could possibly switch to chemical fertilizers, the overall impacts to the environment would not rise to a significant impact at a regional or national level. The proper use and handling of chemical fertilizers, and adherence to manufacturer's recommendations use of chemical fertilizers according to label directions, which is reasonably foreseeable, would result an expected return of water quality to ambient conditions. • The proper use and handling of chemical fertilizers, and adherence to manufacturer's recommendations for using personal protective equipment, are reasonably foreseeable uses of these products and we do not expect significant adverse effects to human health from their use. • The use of chemical fertilizers could cause moderate, but not significant, adverse environmental impacts to soils. Current trends show that other practices such as green manuring, no-till practices, and use of cover crops are growing in popularity. To the extent that these practices are adopted by the agricultural industry, they would help to control the magnitude of the adverse environmental impacts. • If growers choose to comply with the 9-month interval instead of changing the soil amendment type or application method, a minimal (not significant) impact is expected to result from the growing regime or from a reduction in the number of crops a farmer may harvest due to the small number of farms

nationwide that would be impacted. There may be some reduction in farm income if farms need to set aside land or build structures to store the untreated BSAs of animal origin. The amount of produce may be reduced due to a reduced number of harvests per year based on a 9-month waiting period. This may cause an increase in the price of certain produce if supply is reduced and demand is high. However, we expect that any such increase would be prevented by other growers (i.e., regionally, locally, and internationally) filling any gaps in supply. Similar effects would be expected if growers stop growing covered produce, and regional produce commodity prices may increase resulting from a decrease in produce grown in any particular region; however, demand for a certain produce commodity may eventually be met by other growers in the region, growers in other regions (commodity and environment specific), or international suppliers.

- According to FDA estimates (2013b, 2014b), the number of illnesses that would be prevented from finalizing a BSAs of animal origin provision is 244,917; of these illnesses prevented, 156,299 would result from the 9 month application interval with a total health cost benefit of an estimated $14.46 million.

Alternative II: Untreated BSAs of animal origin must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 0 days

- This alternative is similar to the existing condition but with the need to apply in a manner that does not contact covered produce during application.
- If a farmer is allowed to use an interval of 0 days between the application of raw manure and harvest, there is no regulatory need to treat raw manure. Therefore, changes in the type of soil amendment used or crop grown are not anticipated as a result of this management decision. Complying with the 0 day waiting period could require a change in application method for those farms that currently surface treat BSAs of animal origin, as they would need to ensure that it does not contact the covered produce during application.
- Changing the application method to prevent the contact of raw manure with a covered produce crop will potentially require the acquisition of additional equipment. This will require the outlay of funds for the purchase of new equipment and its ongoing maintenance. However, we do not expect a loss of income or employment to result at a significant level on a regional or national level due to the small number of farms potentially affected.
- Beneficial environmental impacts to human health would occur as a result of implementing this alternative, but the benefits would be minimal (not as effective) as compared to the Alternative I.

Alternative III: U.S. Department of Agriculture's organic program application intervals for the use of raw manure as a soil amendment, i.e., 90 days and 120 days before harvest, depending on whether the edible portion of the crop contacts the soil (as specified in 7 CFR 205.203(c)(1))

- With the exception of the short season crops listed in Table 3.4-5 with growing to harvest cycles of 45 days or less, most crops have a growing cycle of about three to four months. For such crops, no changes would be required to management practices in order to comply with this application interval. Additionally, farmers currently in the USDA organic program have adapted their growing practices to be in compliance with this alternative. If a certified organic grower chooses to treat raw manure, the grower will be limited in the choices for treatment in order to maintain its organic status. The small percentage of covered farms which utilize untreated BSAs, as well as the high likelihood that such farms are certified organic growers, indicates that few farms would need to change practices in order to comply with this application interval. As a result, no significant impacts are associated with any management decision under this alternative.
- Other farms that may be associated with marketing agreements that have more stringent application intervals may continue to observe their established standards if they are more stringent than what FDA proposes.
- Some additional public health benefits may occur over the present conditions for farms that may be using a zero-day application rate. The switch to a longer application rate to harvest interval may result

in more (unquantified) foodborne illnesses prevented over Alternative II, but still fewer than what is estimated for Alternative I.

Alternative IV: Untreated BSAs of animal origin must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 6 months

As with Alternative I, given the long interval between application and harvest, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period.

- We would expect proper nutrient management (e.g., proper storage), nutrient management plans, careful selection of application methods, and use of chemical fertilizers according to label directions, will limit any adverse impact to a level that is not significant. With proper use of chemical fertilizers, water quality would be expected to return to ambient conditions.
- If farmers switch to treated manure and the nutrient availability of the treated manures is unknown or difficult to predict, then regular testing would be required. While the current factors may be adequate for general estimating of typical manure nutrient availability, more precise estimates of both nitrogen and phosphorus availability based on compositional analyses are needed to guide producers toward economical and environmentally benign application rates when using treated manures. With proper management, no adverse impact to soil health will occur.
- The use of chemical fertilizers could cause moderate, but not significant, adverse environmental impacts to soils. Current trends show that other practices such as green manuring, no-till practices, and use of cover crops are growing in popularity. To the extent that these practices are adopted by the agricultural industry, they would help to control the magnitude of the adverse environmental impacts. The production and transport of chemical fertilizers may have an adverse but not significant impact on energy use and air quality because the resource use is not expected to change substantially as compared to current baseline conditions and, therefore, the impacts to public health from air emissions would not rise to a significant impact at a regional or national level
- Changing the application method to prevent the contact of raw manure with a covered produce crop may require the acquisition of additional equipment, which would equate to a one-time outlay of funds for the purchase of new equipment and its ongoing maintenance. However, we do not expect a loss of income or employment to result at a significant level on a regional or national level due to the small number of farms potentially affected. Similar to Alternative I, if growers chose to switch to a non-covered crop, regional produce commodity prices may increase, resulting from a decrease in produce grown in any particular region; we consider such impacts unlikely, however, as demand for a certain produce commodity would likely be met by other growers in the region, growers in other regions (commodity and environment specific), or international suppliers.
- This alternative may result in improved public health benefits over Alternatives II and III but less than Alternatives I or V, due to the longer application-to-harvest interval.

Alternative V: Untreated BSAs of animal origin must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 12 months

- As with Alternatives I and IV, given the long interval between application and harvest, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period. Switching to treated material would reduce the interval between application of the treated manure and harvest to 0 days, rather than the interval of 12 months for the use of raw manure.
- Impacts under Alternative V would be substantially similar to those described under Alternatives I and IV.
- This alternative may result in improved public health benefits over all other alternatives due to the longer application-to-harvest interval. Several marketing agreements already observe a similar minimum application interval.

Treated BSAs
Alternative I: As proposed. Minimum application interval of 0 days
• This alternative is similar to the current baseline conditions. No impacts would be associated with this alternative and corresponding management decisions. The use of chemical fertilizers in place of treated BSAs of animal origin as a nutrient source is unlikely to occur under this alternative because the alternative does not restrict the timing of the use of BSAs, but contains the requirement that the treated BSAs of animal origin be applied in a manner that does not contact covered produce.
Alternative II: Minimum application interval of 45 days
• With the exception of the short season crops listed in Table 3.4-6 with growing to harvest cycles of 45 days or less, most crops have a growing cycle of about three to four months. Therefore, for most crops, an application interval of 45 days would not require any changes in the soil amendment type in order to comply with the requisite waiting period. Because this alternative is largely representative of the existing condition, no significant environmental impacts would be associated with this alternative and corresponding management decisions.
Alternative III. Minimum application interval of 90 days
• As discussed under Alternative II, most crops have a growing cycle of about three to four months. Therefore, an application interval of 90 days would not require any changes in the soil amendment type in order to comply with the requisite waiting period. No significant environmental impacts would be associated with this alternative and corresponding management decisions.

Subpart I: Standards directed to domesticated and wild animals

Table 4-6 presents a summary of potential impacts and comparison of alternatives under subpart E, as discussed in Chapter 4.5 and 4.6.

Table 4-6. Summary and comparison of alternatives under subpart I

Grazing
Alternative I Adequate waiting period
• Given that only approximately 2,829 dual- or multi-purpose farms both raise livestock or poultry and grow produce (and some smaller subset of this number grows covered produce), the overall regional and nationwide potential environmental impacts from grazing operations would be minimal. This provision is expected to affect between 1.5 and 8 percent of growers of covered produce. • Any measures taken to permanently exclude domestic animals (although not required by the rule) from covered produce would not have significant environmental impacts relative to a waiting period for harvesting covered produce. Although there may be some measures such as fencing (not required by the rule) that farmers without fencing now may establish to exclude domesticated animals, any potential environmental impacts are not expected to be significant. Related impacts to fencing could include clearing a border around the farm field, thereby potentially removing vegetation. Reduced access to forage and cover for wildlife species due to the fencing or other exclusion measures may disrupt the existing wildlife corridors of transient terrestrial animal species, but few such disruptions are anticipated because exclusion measures could be ineffective to prevent wildlife from entering farm fields and because general impacts to wildlife habitat would be limited to the borders of the fields where such exclusion measures may be implemented. • The application of chemicals such as herbicides to control vegetation around farm fields, and the application of insecticides/pesticides to control other pests could result in adverse effects to water quality. However, when applied in accordance with their labeling requirements, which would be a reasonably foreseeable use, the impacts are not expected to be significant, and water quality conditions

would be expected to recover to ambient conditions. The quantities of air emissions and GHGs related to fencing or other exclusion measures are not expected to result in public health concerns because there would be no measureable change to the air quality environment over existing conditions. In addition, all of these aforementioned impacts take into consideration the very small number of farms potentially affected by this provision where such impacts may occur.

- The more likely management decision would be to factor in the crop and region in which the crops are grown to allow for consideration of late growing seasons and other factors when determining when to remove the animal from the field at some time during the planting to harvest interval. Unlike Alternatives II and III, this alternative provides flexibility for farmers to make the decision on an appropriate time interval, based on the farm's operation.
- Because such dual-purpose operations are mostly anticipated to have confined grazing or other areas for livestock already (livestock management does not occur in produce fields, as livestock, if allowed to graze in produce fields would consume much of the commodity), removing the animal from fields where covered produce may be grown, relative to a planting/harvest interval, is not anticipated to result in adverse impacts (other than what is presently experienced) to either the produce field or to the field(s) to which the animal is confined.
- Any measure taken to reduce the hazard from pathogen transport to produce is expected to result in beneficial impacts to human health; however, relative to a permanent exclusionary measure, a management decision to include an adequate waiting period before using a field for growing covered produce may have less human health benefits (i.e., in terms of foodborne illnesses prevented) compared to creating a barrier to animal entry and grazing entirely. A notable exception to human health benefits could be the use and handling of chemicals as part of a strategy to exclude domestic animals from farm fields. However, as discussed in Chapter 4.1, the proper use and handling of such chemicals, and adherence to manufacturer's recommendations for using personal protective equipment, are reasonably foreseeable uses of these products and we would not expect significant adverse effects to human health from these uses.

Alternative II: Waiting period of 9 months

- As compared to Alternatives I and III, there are no substantially different impacts that can be estimated at a regional or national level, and, in addition, all alternatives take into consideration the very small number of farms to which this provision would apply.

Alternative III: Waiting period of 90/120 days

- As compared to Alternatives I and II, there are no substantially different impacts that can be estimated at a regional or national level, and, in addition, all alternatives take into consideration the very small number of farms to which this provision would apply.

Animal Intrusion

Alternative I: Evaluate whether produce can be harvested safely

- Under Alternative I, there would be no significant adverse impacts expected with respect to any specific resource component.
- Evaluating whether produce can be harvested safely and, as appropriate, not harvesting a field or part of a field that is reasonably believed to be contaminated from wildlife intrusion would have no environmental impacts to water resources, waste generation, disposal, and resource use, and air quality. There may be minimal, non-significant beneficial environmental impacts observed to wildlife species as a result of added short-term cover and forage area from not harvesting part of the field and to soils from nutrients and carbon that would be reincorporated into the soils and lengthened surface cover to maintain or improve soil health.
- In terms of reducing pathogens, impacts are expected to be beneficial. Requiring the farmer to evaluate whether or not covered produce should be harvested based on the likelihood of being contaminated by animal intrusion would reduce potential pathogenic exposure to consumers. If the farmer does not

harvest the field or part of the field in order to avoid harvesting contaminated covered produce, there would be a moderate beneficial impact on human health and safety.

- Chemicals used in exclusion measures may result in adverse effects to human health for the farmworkers that may be applying the chemical treatments. However, with the proper use and handling of such chemicals, in accordance with the manufacturer's labeling requirements (including heeding recommendations or requirements for personal protective equipment such as chemical-resistant gloves), we do not expect these impacts to human health and safety to be significant.

Alternative II: Measures to exclude wildlife

- As compared to Alternative I, environmental impacts would be greater.
- Measures to exclude wildlife (including measures to clear land to facilitate monitoring) may involve the use of herbicides, rodenticides, or other materials that may have short-term toxic effects to water resources, biological resources and ecosystems directly adjacent to the farm, and soils. These impacts may be minimized through proper use and handling in accordance with labeling requirements, as EPA, in cooperation with states, carefully regulates these chemicals to ensure they do not pose an unreasonable risk to human health or the environment. EPA requires manufacturers to conduct extensive testing in order to identify any potential risks, and the agency carefully reviews these data provided by manufacturers before the product may be registered for use. Therefore, we do not anticipate significant adverse effects associated with these products. The overall environmental impacts would be limited because the chemical components generally quickly dissipate or decompose, and do not persist in the environment. Measures that may be employed to reduce any other potential adverse effects that may otherwise be significant include preparing pest management plans that are discussed earlier in this chapter.
- Hunting, trapping, and animal poisoning are other methods that are sometimes used to manage wildlife species at or adjacent to farm fields. Hunting and trapping are often accomplished in accordance with state or county permit requirements and in accordance with state wildlife regulations, which factor in species population levels before determining the number of licenses/permits that can be issued without adversely impacting the species survivability (USFWS, 2000). For example, deer damage permits may be available to farmers that have experienced crop damage as a result of deer entering their production fields. These permits allow for the shooting of a specified number of deer during a certain period, usually outside of the normal hunting season.
- Under this alternative, proposed § 112.84 could also state that Part 112 does not require covered farms to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.
- Costs under Alternative II would be higher than what would be expected under Alternative I.
- In terms of reducing pathogens, impacts are expected to be beneficial. Chemicals used in exclusion measures may result in adverse effects to human health for the farmworkers that may be applying the chemical treatments. However, with the proper use and handling of such chemicals, in accordance with the manufacturer's labeling requirements (including heeding recommendations or requirements for personal protective equipment such as chemical-resistant gloves), we do not expect these impacts to human health and safety to be significant.

Subpart A: General Provisions (Scope of Coverage of the Proposed Rule); includes impacts related to the aggregate effects of each proposed standard assessed together

As discussed at the beginning of Chapter 4.7, this comparison of aggregate environmental impacts under subpart A is accomplished by considering the alternatives that would best fulfill FDA's statutory mission and responsibilities. For subpart E, the added flexibility to meet a generic *E. coli* water quality standard for all covered produce (including root crops) is best represented by Alternative IV-a. For subpart F untreated BSAs of animal origin, where FDA has signaled its intent to defer finalization of a standard, the zero days standard, or Alternative II, is used for purposes of this evaluation. Subpart F (treated BSAs of animal origin) is best represented by Alternative I. Subpart I (Grazing), Alternative I, observing an adequate waiting period is the alternative that would best fulfill FDA's statutory mission and responsibilities, as growers would be able to factor in the crop and region in which the crops are grown to allow for consideration of late growing seasons and other factors when determining when to remove the animal from the field at some time during the planting to harvest interval. For subpart I (Animal Intrusion), Alternative I would best fulfill FDA's statutory mission and responsibilities. Requiring the farmer to evaluate whether or not covered produce should be harvested based on the likelihood of being contaminated by animal intrusion would reduce potential pathogenic exposure to consumers, as compared to exclusion measures such as fencing, which may be an ineffective means of keeping wildlife from the farm field.

Water Resources-

- Significant current and ongoing adverse impacts such as reduced water availability, water-table declines, soil subsidence and increased costs for finding and maintaining access to water, resulting from groundwater withdrawals, are presently experienced in regions B, C, D, I, J, and U. These impacts represent the current condition, absent of any final rule, and are the result of many factors that include agricultural practices nationwide, development, and other factors unrelated to FDA's proposed action. Any action (personal, federal, state, local, etc.) in these regions that would cause a farmer or any entity to draw from groundwater instead of surface water could exacerbate the current environmental conditions. Such impacts could also be felt in regions in the northeastern and northcentral reaches of Mexico that share an aquifer near the border of regions D, I, or J in the United States. Under such conditions, individuals on Native American reservations in regions B and C may be disproportionately adversely impacted as a result of continued groundwater drawdown. We consider impacts from actions that result in groundwater drawdown to be significant in regions where current conditions for groundwater depletion have significant environmental impacts. Such impacts are considered under the cumulative impacts section, Chapter 5.
- The flexibility in meeting the proposed water quality standard is likely to reduce the need to use chemical treatment of a water source with poor water quality. It is also likely that a farmer might add a post-harvest mechanism to allow for added microbial die-off or removal in lieu of treating the water source.
- It is not likely that a farmer will change the water source or cease growing covered produce because among the regions that are potentially most affected (B, C, D, I, J, and U), many farmers have entered into marketing agreements that establish numeric standards that are the same as, or are more stringent than, those proposed in the PS PR. In general, the existence of these marketing agreements, particularly in produce growing regions currently experiencing water impacts,

minimizes the severity of potential impacts on resource components. In addition, reactions and verbal comments from some industry and trade groups that FDA received on the supplemental proposed rule suggest that the new proposed provisions for microbial die-off and removal to achieve the proposed microbial quality standard considerably reduce the perceived need to change water source in order to comply with Alternative IV-a. Any action that may lead to increases in groundwater drawdown would be considered a significant environmental impact. Regions that may be most impacted in terms of potential land subsidence, including any additive effects by switching to groundwater sources, include the regions that already experience the highest groundwater withdrawals; these are regions B, C, D, I, J, and U, as well as corresponding areas in the northeastern and northcentral region of Mexico that share an aquifer with region D, I, or J in the United States.

- The majority of the 285 covered sprouting operations draw from municipal water already. Only minimal adverse, local and not significant impacts may occur from water treatment effluent, and no nationwide or regional impacts are anticipated to water availability from those few operations that may connect to municipal water supplies.
- With respect to water quality and impacts considered under subpart F (untreated or treated), if a farmer is permitted to use an application interval of 0-days between the application of untreated or treated manure and harvest, there would be no substantial change from the baseline condition that would result in additional impacts to water quality or availability.

Biological and Ecological Resources-

- Adverse effects to biological and ecological resources relevant to groundwater drawdown are not expected (discussed above). A high number of growers in key growing regions, such as California, Arizona, and Florida (Regions C, D, and U), already participate in marketing agreements that have more stringent numeric water quality standards than what FDA has proposed, and are already using water that would be in compliance with the proposed standard.
- With respect to subpart I (grazing) the more likely management decision would be to factor in the crop and region in which the crops are grown to allow for consideration of late growing seasons and other factors when determining when to remove the animal from the field at some time during the planting to harvest interval, which provides flexibility for farmers to make the decision on an appropriate time interval, based on the farm's operation. Because such dual-purpose operations are mostly anticipated to have confined grazing or other areas for livestock already (livestock management does not occur in produce fields, as livestock, if allowed to graze in produce fields would consume much of the commodity), removing the animal from fields where covered produce may be grown, relative to a planting/harvest interval, is not anticipated to result in adverse impacts (other than what is presently experienced) to either the produce field or to the field(s) to which the animal is confined. With respect to subpart I (wildlife intrusion), the most likely management decision would be to evaluate whether produce can be harvested safely and, as appropriate, not harvest a field or part of a field that is reasonably believed to be contaminated from wildlife intrusion.
- We would not expect environmental impacts to water resources, waste generation, disposal, and resource use, and air quality associated with this management decision.
- For subpart I taken together, any measures, however unlikely, taken to exclude animals (including measures to clear land to facilitate monitoring) may involve the use of herbicides, rodenticides, or other materials that may have short-term toxic effects to water resources, biological resources and ecosystems directly adjacent to the farm, and soils. These impacts may

be reduced through proper use and handling of such chemicals in accordance with labeling requirements, which would be a reasonably foreseeable use (see Chapter 4.1 and 4.2). Water quality conditions would be expected to recover to ambient conditions. Wildlife, vegetation, and wetlands would be resilient to the effects of the chemicals at a regional or national level. The quantities of air emissions and GHGs related to fencing or other exclusion measures are not expected to result in public health concerns because there would be no measureable change to the air quality environment over existing conditions. In addition, all of these aforementioned impacts take into consideration the very small number of farms potentially affected by this provision where such impacts may occur (at most 8 percent of covered farms). Measures that may be employed to reduce any other potential adverse effects that may otherwise be significant include preparing pest management plans. Such plans are discussed earlier in this chapter. Additionally, proposed § 112.84 does not require covered farms to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. The alternative and more likely management decision that farmers may make, is to monitor their fields and evaluate whether produce can be harvested safely. As discussed above, any unharvested portions of the field may provide non-significant beneficial impacts to wildlife species as a result of added short-term cover and forage area.

- Hunting, trapping, and animal poisoning are other methods that are sometimes used to manage wildlife species at or adjacent to farm fields. Hunting and trapping are often accomplished in accordance with state or county permit requirements and in accordance with state wildlife regulations, which factor in species population levels before determining the number of licenses/permits that can be issued without adversely impacting the species survivability (USFWS, 2000).

Soils-

- The added flexibility in meeting the proposed water quality standard is likely to reduce the need to change the water source; therefore, the aggregate impacts should not have direct effects on soils.
- However, as described in Chapter 3.3.3.4, the USGS has identified that more than 80 percent of the identified land subsidence in the nation is a consequence of groundwater exploitation. In many areas of arid western regions and in more humid areas underlain by soluble rocks such as limestone, gypsum, or salt, land subsidence is an often overlooked environmental consequence of land- and water-use practices. Figures 3.1-23 and 3.1-24 show the extent of excessive groundwater pumpage of aquifer systems throughout the U.S. which correlate to areas where land subsidence is most likely to occur. Actions that would increase reliance on groundwater would potentially also impact soils. An impact on soils resulting from groundwater drawdown may result in impacts that are in addition to, but related to, irreversible compaction or subsidence, such as reduced ability to partition water for groundwater recharge and for use by plants and soil organisms. Regions where groundwater withdrawal may have the highest influence on land subsidence, and thus permanent damage to soils, are B, C, D, I, J, and U, as well as regions in the northeastern and northcentral reaches of Mexico that share an aquifer with regions D, I, or J. Therefore, impacts on groundwater resources, where steps are not taken to reduce the impacts as discussed in Chapter 3.1.3.11, may result in irreversible impacts on soils and corresponding impacts on the ability of those soils to filter nutrients, chemicals and pathogens.

- With respect to soil health and impacts related to subpart F (untreated or treated), if a farmer is permitted to use an application interval of 0 days between the application of untreated or treated manure and harvest, there would be no substantial change from the baseline condition that would result in significant impacts to soil resources.
- With respect to subpart I (grazing and wildlife intrusion taken together), in most cases, covered dual- or multi-purpose operations already have fields that are dedicated pasturelands and would not, under normal conditions, be rotated in for crop land. Any impacts to soils in these areas are most likely already occurring; therefore, no significant impacts from grazing are expected on soils under any management decision or alternative as a result of the PS PR, if finalized.

Waste Generation, Disposal and Resource Use-

- (Untreated) As discussed above, if a farmer is permitted to use an application interval of 0 days between the application of untreated manure and harvest, there would be no substantial change from the baseline condition that would result in significant impacts to waste generation, disposal, or use of the resource.
- (Treated) The proposed condition would be similar to the existing condition. No impacts would be associated with this alternative and corresponding management decisions. The use of chemical fertilizers in place of treated BSAs of animal origin as a nutrient source is unlikely to occur under this alternative because the alternative does not restrict the timing of the use of BSAs, but would impose a requirement to apply in a manner that does not contact covered produce.

Air Quality and Greenhouse Gases-

- There are minimal adverse environmental impacts (not significant) associated with air quality and GHGs are not expected to contribute to air emissions of criteria pollutants or GHG emissions that may result in considerable public health concerns at a regional or national level.

Socioeconomic and Environmental Justice-

Major cost summary

As discussed previously, potential socioeconomic impacts related to the socioeconomic resource component that are associated with meeting the requirements for the provisions of the PS PR, if finalized, could stem from economic costs that result from management decisions to comply with the standards. In addition, FDA would consider estimates prepared by FDA in the 2014 supplemental regulatory impact analysis (2014b) in its consideration of environmental alternatives (see 40 CFR 1502.23). The 2014 economic impact analysis put the total cost of implementing the provisions of the PS PR (2013 proposed rule and supplemental notice, taken together) at $386.23 million nationwide for businesses with an average annual monetary value of produce sold during the previous three-year period of more than $25,000 (FDA, 2014b). Table 4-7 breaks down these costs by provision and by size class of farm.

Table 4-7. Summary of costs for the PS PR (in millions)

Cost Sections	Not Covered	Very Small	Small	Large	Total	Original	Difference
Administrative cost to learn the rule	$11.50	$14.34	$6.09	$7.17	**$39.10**	$36.79	$2.31
Health and Hygiene	$0.00	$23.24	$12.88	$82.06	**$118.17**	$138.21	-$20.04
Agricultural Water	$0.00	$20.29	$4.84	$11.10	**$36.23**	$48.55	-$12.32
BSAs of Animal Origin	$0.00	$0.00	$0.00	$0.00	**$0.00**	$9.20	-$9.20
Domesticated and Wild Animals	$0.00	$8.82	$5.10	$18.38	**$32.30**	$37.78	-$5.48
Growing, harvesting, packing, and holding activities	$0.00	$0.15	$0.08	$0.14	**$0.36**	$0.42	-$0.06
Equipment, tools, buildings, and sanitation	$0.00	$9.73	$7.03	$33.58	**$50.34**	$58.87	-$8.53
Sprouting operations	$0.00	$0.64	$0.61	$5.19	**$6.44**	$7.53	-$1.09
Personnel Qualifications and Training	$0.00	$16.76	$10.98	$50.43	**$78.17**	$91.42	-$13.25
Corrective steps	$0.00	$0.41	$0.19	$0.85	**$1.44**	$2.09	-$0.65
Variances	$0.00	$0.00	$0.01	$0.01	**$0.08**	$0.10	-$0.02
Recordkeeping	$0.00	$13.36	$3.47	$6.76	**$23.59**	$28.60	-$5.01
Total Costs (annual in millions)	$11.50	$107.73	$51.26	$215.73	**$386.23**	$459.56	$73.33
Average Cost per Farm	$88	$4,477	$12,384	$29,545	**$10,996**	$11,430	-$433.65

Source: FDA, 2014b

Notes: Costs presented are annualized over 7 years at 7%. The costs of almost all of these categories have fallen from those originally proposed, due to either reduced requirements or a smaller number of covered farms estimated to incur costs. The sole exception is the total costs to farms not covered by the supplemental proposal. The costs to this group have grown simply because we now estimate there are more farms that would not be covered or would qualify for an exemption; the per-farm costs to this group have not changed.

The average projected per-farm cost of complying with the provisions of the PS PR is approximately $11,000, though this estimate is much lower (i.e., approximately $4,500) for very small farms. Small and very small farms may not be able to afford the added cost burden of complying with the provisions of the PS PR. It is anticipated that these farms, if they are not able to qualify for an exemption to reduce the cost of compliance, would be the most likely to make management decisions that would result in them not being subject to the provisions of the PS PR.

As discussed under Chapter 4.2, based on the comments FDA has received in response to the 2013 proposed rule and supplemental proposed rule, FDA does not expect farmers to decide to cease growing covered produce as a preferred management decision except in select instances which are often driven by outside pressures such as a program run by the state of California that pays farmers to keep land fallow in order to divert water to the cities. This is not a re-zoning of the land; rather, that land is essentially reserved for future alternative agricultural uses. FDA received additional comments during the comment period for the Draft EIS on the likelihood of such a management

decision to occur; however, nothing in those comments changes the conclusions made in this section of the Final EIS.

If non-covered produce or other agricultural crops that are not produce are grown, requirements to maintain certain water quality conditions would be dependent on any existing state regulations or industry marketing agreements. The type of crop a farmer may select to grow would also be dependent upon the region's climate, soils, water availability, and may involve a decision whether the existing farm's equipment and infrastructure would be sufficient, or would need to be updated, modified, or bought to accommodate a new type of crop.

Under certain conditions, where very small farms are involved and costs may be a larger factor, some farms may decide to stop growing crops altogether. However, this scenario would be most likely for very small farms as well as livestock operations that grow small amounts of covered produce (although many such diversified farming-livestock operations would likely be excluded based on the new proposed monetary threshold for excluded farms applied to sales of produce only rather than sales of food). There are no data to suggest under what conditions specifically such a management decision may occur, and there are no data available to quantify or qualify any related indirect impacts.

Also related to subpart E, there may be additional costs (and associated socioeconomic impacts) from those projected in FDA's PRIA (FDA, 2013b and 2014b) if farmers add a post-harvest mechanism (e.g., FDA-approved wash or rinse) to achieve microbial die-off or removal.

Under subpart F, since there is no substantial change from the existing conditions, we do not expect additional costs (and associated socioeconomic impacts) associated with this provision.

Environmental justice –
Minority groups: The overall cost of compliance for farms could potentially result in higher produce prices for consumers, including minority consumers. However, we expect that demand for produce commodities would eventually be met by other growers in the region, growers in other regions, or international suppliers. As a result, we expect commodity prices to stabilize.

As discussed in Chapters 1.9, 3.7, and 4.1, Environmental Justice impacts related to the PS PR are assessed for minority principal operators and minority farmworkers.

When considering the thresholds established in Chapter 3.7 for identifying potential impacts to minority principal operators, regions that are important for identifying potential impacts to minority principal operators are regions A, B, C, D, W, and V. Of these regions, regions B and C are major produce growing regions (see Chapter 1.7). Information for minority farmworkers is provided below.

<u>Principal operators</u>
Like all principal operators, minority principal operators would need to make management decisions regarding whether to comply with the provisions of any final rule or to cease growing covered produce. As noted above, very small farms are more likely than larger farms to decide to stop growing covered produce altogether if the farm manages livestock operations that also grow

small amounts of covered produce; many such diversified farming-livestock operations would likely be excluded based on the proposed monetary threshold for excluded farms applied to sales of produce only rather than sales of food. Based upon the "meaningfully greater" threshold FDA established for minority populations of principal operators potentially affected by the rule, regions where minority principal operators manage very small farms that are more likely to make a management decision to cease growing covered produce are regions A, B, C, D, W, and V.

Minority farmworkers

Based on the limited information on farmworkers reported by the DOL through surveys taken by that agency (see Chapter 3.7.3), regions where there are potentially populations of minority farmworkers that may be impacted by the rule, if finalized, include regions C, D, I, and J. Costs incurred by farms of all sizes may result in the farm either increasing the costs of their produce for consumers, or may involve the farm principal operator terminating the employment of full-time, part-time, or seasonal worker(s) in order to defray their operating costs. With respect to the scope of this EIS (see Chapter 1.9), regions where such actions may adversely disproportionately affect minority farmworkers due to employment-related impacts, include regions C, D, I and J.

Native American operators: Of all farms that are operated by Native American principal operators, whether located on or off reservations, 5.5 percent report growing vegetables, 2.4 percent report growing fruits and tree nuts, and 15 percent report growing combination crops. There may be farms that produce crops in multiple of these categories, and these categories include both covered and non-covered crops. Therefore, based on a very conservative estimate, no more than 22.9 percent of farms—the sum of these three categories—that are operated by Native American principal operators may be growing covered produce (USDA NASS, 2014a). Based on USDA NASS data (2014a), 78 percent of all Native American farms sell less than $10,000 in total sales, annually, meaning that, at most, 22 percent of farms with a Native American principal operator would be covered farms under the PS PR, if finalized. If we assume that these trends are consistent across all commodities, this means that, at most, 5 percent of farms with a Native American principal operator would be covered by the rule (22 percent of 22.9 percent is approximately 5 percent). Moreover, farms that sell less than $25,000 annually in produce—not $10,000—are not covered by the PS PR. An additional 14 percent of farms with a Native American principal operator sell less than $49,999, meaning there is a reasonable likelihood that additional farms with a Native American principal operator would not be covered by the PS PR, if finalized. It is not possible to estimate what percent of farms lie between $10,000 and $49,999 average annual sales. An additional 5 percent of Native American operated farms have less than $249,999 in total sales.

Despite the low number of total Native American owners/operators who may be covered by the rule, there is a potential that added operating costs associated with the rule would impact a disproportionate number of Native American farmers compared to farmers as a whole, given that the average income for a farm for which a Native American is the principal operator is 30 percent lower than a farm for which the principal operator is not a Native American (per the 2007 Agricultural census). The average reported agricultural product sales for Native American operated farms is $40,331, compared to an average of $134,807 for all farms. The average potential per farm cost of approximately $4,500 for very small farms could be disproportionally burdensome for farms with a Native American principal operator, as this cost would comprise approximately

11 percent of average annual sales, compared to 3 percent of the average annual sales of all farms.[27] However, the potential impacts for very small and small farms may be entirely mitigated to the extent these farms are eligible for a qualified exemption.

Low-income: As discussed in chapter 3.7.3, this class includes any persons whose median household income is at or below the HHS poverty guidelines. The poverty threshold for a family of four in 2012 was set at $23,050. According to the ERS's data sheet, *Principal Farm Operator Household Finances by ERS Farm Typology*, in 2012, median farm operator household income, an average of the farm and off-farm household incomes of residence farms, intermediate farms, and commercial farms, was $68,298.[28] This exceeds both median U.S. household income, and the HHS poverty thresholds for all HHS poverty thresholds. While there may be low-income principal operators that may be adversely impacted by the costs associated with the rule, we cannot identify a low-income population on a national or regional level.

Low-income farmworkers: As discussed under minority farmworkers, impacts may involve the farm principal operator terminating the employment of full-time, part-time, or seasonal worker(s) in order to defray their operating costs. Consistent with the scope of the EIS (see Chapter 1.9), based on data provided by the DOL (information reported for California) (DOL, 2000 and 2005), region C has populations of low-income farmworkers that may be disproportionately impacted by the rule. Note that other regions may experience similar impacts, but there is not enough data available to understand which regions may specifically be impacted.

Human Health-

Foodborne illnesses prevented

FDA estimates, in the 2014 PRIA to the PS PR, that the number of foodborne illnesses prevented when considering the rule as proposed, all provisions, is 1.57 million, annually (FDA, 2014b). This represents a significant beneficial outcome to human health because the rule as proposed is likely to minimize the risk of serious adverse health consequences or death from covered produce.

Human health impacts

Under subpart E, EPA-registered pesticide products are evaluated to determine potential environmental effects and potential impacts to human health specific to their use. With respect to the use of chemical pesticides, FIFRA mandates that EPA regulate the use and sale of pesticides to protect human health and preserve the environment. There is the possible risk of chemical exposure to site workers that may have to handle pesticides prior to application, but these risks are minimized when using proper handling techniques including using recommended personal protective equipment in accordance with labeling requirements or product recommendations (e.g., chemically resistant gloves to avoid exposures that may otherwise cause unreasonable health effects) as described by the manufacturer. We do not expect impacts to human health and safety to be significant from the use of these products.

[27] $4,500 divided by $40,331 equates to approximately 11 percent.

[28] There is limited data for principal farm operator income other than on a national level.

4.7.1 Alternatives Analysis

By applying the potential environmental impacts from each of the alternatives that would best fulfill FDA's statutory mission and responsibilities (see above), we may now identify the potential environmental and related socioeconomic impacts to each of our alternatives that were first identified in Chapter 2.1 Subpart A. A comparison of potential impacts is provided below and summarized in Table 4-8.

Table 4-8. Comparison of potential impacts by alternative for subpart A

		≤ $25,000 * total produce excluded Alternative I	≤ $50,000** Food excluded Alternative II	≤ $100,000** Food excluded Alternative III	≤ $25,000 covered produce excluded Alternative IV
Comply with the rule	Covered Farms	35,503	28,253	20,140	Slightly fewer than Alternative I
	Excluded Farms	130,204	161,384	169,497	Slightly greater than Alternative I
	Environmental impacts (Chapters 4.1 – 4.7)	Greater than baseline	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Economic impacts (domestic costs annually)	$540.49 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Domestic benefits (health-related cost savings)	$930 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Public health benefits (foodborne illnesses prevented annually)	1.57 million	Less than Alternative I (less foodborne illnesses prevented)	Less than Alternative II (less foodborne illnesses prevented)	Slightly fewer than Alternative I (more foodborne illness prevented)
Switch to non-covered crop	Covered Farms	Less than 35,503	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Excluded Farms	Greater than 130,204	Greater than Alternative I	Greater than Alternative II	Slightly greater than Alternative I
	Environmental impacts (Chapters 4.1 – 4.7)	Less impacts compared with complying	Less impacts compared with Alternative I	Less impacts compared with Alternative II	Slightly fewer than Alternative I
	Economic impacts (domestic costs annually)	Less than $540.49 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Domestic benefits (health-related cost savings)	Less than $930 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Public health benefits (foodborne illnesses prevented annually)	Less than 1.57 million	Less than Alternative I (less foodborne illnesses prevented)	Less than Alternative II (less foodborne illnesses prevented)	Slightly fewer than Alternative I (more foodborne illness prevented)

**As updated in the 2014 supplemental PRIA (FDA, 2014b).*
***The associated estimates are found within the 2013 PRIA (FDA, 2013b).*

Under Alternative I more farms would be covered than if the average annual monetary value threshold for exclusion of farms were higher (as in Alternatives II and III) or if the threshold was changed to covered produce only (as in Alternative IV).

For any alternative the expected environmental outcome may be as follows:

- Significant current and ongoing adverse impacts such as reduced water availability, water-table declines, soil subsidence and increased costs for finding and maintaining access to water, resulting from groundwater withdrawals are presently experienced in regions B, C, D, I, J, and U, and represent the current condition, absent of any final rule. Any action in these regions that would cause a farmer or any entity to draw from groundwater instead of surface water could exacerbate the current environmental conditions in these regions, generally, or in corresponding regions in the northeastern and northcentral reaches of Mexico that share an aquifer with regions D, I, or J. Under such conditions, individuals on Native American reservations in regions B and C may be disproportionately adversely impacted as a result of continued groundwater drawdown. We consider impacts from actions that result in groundwater drawdown to be significant in regions where current conditions for groundwater depletion have significant environmental impact. Such impacts are best considered under the cumulative impacts section, Chapter 5. However, such impacts are not expected to occur as a result of this rule based on the flexibility in meeting the proposed water quality standard (see the following bullets). The flexibility in meeting the proposed water quality standard is likely to limit the need to use chemical treatment of a water source with poor water quality. It is also likely that a farmer might add a post-harvest mechanism to allow for added microbial die-off or removal.
- Moreover, reactions and verbal comments from industry and trade groups that FDA has received on the supplemental proposed rule suggest that the new proposed provisions for microbial die-off and/or removal to achieve the proposed water quality standard considerably reduce the perceived need to change water source in order to comply with Alternative I under subpart E. In addition, many farmers have entered into marketing agreements that are the same as, or operate under more stringent numeric water quality standards than, those proposed in the PS PR. FDA received no conflicting comments to the same topic during the Draft EIS public comment period.
- Other environmental impacts nationwide are expected to be not significant, with the exception of human health and safety where there would be significant beneficial outcome to human health. Impacts associated with biological and ecological resources may potentially result from the use of chemical treatments (e.g., pesticides, herbicides); however, wildlife, vegetation, and wetlands would be resilient to these impacts. There are minimal adverse environmental impacts (not significant) associated with air quality and GHGs are not expected to contribute to air emissions of criteria pollutants or GHG emissions that may result in considerable public health concerns at a regional or national level.

Therefore, given this analysis, FDA expects the PS PR, if finalized as proposed, would have significant adverse environmental impacts on groundwater and soil resources that are reviewed within the scope of this EIS.

For any alternative where fewer farms are covered by the rule (fewer than Alternative I), the potential outcomes may be as follows:

- The expected costs of complying with the rule nationwide would decrease but the expected per farm costs are anticipated to remain the same as Alternative I.
- The expected environmental impacts, both adverse and beneficial, would decrease nationwide, but not to the extent that would reduce any significant impacts to a less than significant level.

- The expected number of foodborne illnesses would decrease, which means fewer public health benefits would be experienced.

4.8 Preferred Alternative

This section addresses the Agency's preferred alternative. As defined by the Council on Environmental Quality (CEQ), the "agency's preferred alternative" is "the alternative which the agency believes will fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors" (CEQ, 1981). The concept of the "agency's preferred alternative" is different from the "environmentally preferable alternative," although in some cases an alternative may be both. As previously discussed, given the diverse nature of agricultural practices, we analyzed the potential impacts of alternatives for each of the potentially significant provisions both individually and cumulatively. This analysis allowed for a more comprehensive understanding of the role that each of the provisions plays in terms of environmental impacts and human health benefits.

FDA used a two-step process to identify the preferred alternative for the Final EIS. In the first step, FDA established a range of reasonable alternatives for each potentially significant provision. Each alternative reflects a science-based minimum standard established for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities, to minimize the risk of serious adverse health consequences or death (see 21 U.S.C. 350h(a)). At the second step, FDA selected the alternative for each provision for use in the aggregate analysis in Chapter 4.7 that FDA believes would best "fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors" (CEQ, 1981), with the exception of untreated BSAs of animal origin. FDA has previously indicated it would defer decision on a minimum application interval for untreated BSAs of animal origin and therefore has not identified an alternative that would best meet the statutory mission and responsibilities. For the purpose of the aggregate analysis, in the absence of a decision on the alternative which would fulfill the statutory mission, the impacts associated with the 0-day application interval were included as the environmental impacts associated with this alternative. Such impacts are indicative of current practice and any minor shifts in this practice that may be anticipated.

FDA considered the management decisions that were analyzed for each potentially significant provision in Chapter 4. Chapter 4.7.1 contains FDA's analysis of the most likely management decisions to occur under subpart A, as well as the alternatives that would best fulfill FDA's statutory mission and responsibilities.[29] The rationale for each alternative is discussed in detail for subparts E, F, I, and A in the section that follows. Management decisions were identified in consultation with USDA and after consideration of public comment on the PS PR.

[29] As discussed in Chapter 4.7, unlike with standards directed at specific potential routes of pathogen introduction (*e.g.*, subparts E, F, and I), proposed § 112.4 in subpart A establishes the value of produce sold above which a farm growing covered produce would be subject to the provisions of the rule (i.e., covered farms). Covered farms would be required to either comply with the provisions of the rule, including through the use of the management decisions described in Chapters 4.2 through 4.6, or switch to crops that are not covered by the proposed rule. In other words, complying with the rule would mean that a farmer would have to abide by the provisions of the rule, except where the grower would qualify for certain exclusions from coverage of the rule.

Taken together, the Agency's preferred alternative for the Final EIS can be summarized and stated as follows:

Except in cases where the grower would qualify for certain exclusions from coverage of the rule, if you are a farm or farm mixed-type facility with an average annual monetary value of produce (as defined in proposed 21 CFR 112.3(c)) sold during the previous 3-year period of more than $25,000 (on a rolling basis), you are a "covered farm" that must comply with the provisions of 21 CFR part 112 when conducting a covered activity on "covered produce" (proposed 21 CFR 112.4, as amended by the supplemental proposed rule), including:

1) When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method that includes root crops that are irrigated using low-flow methods such as drip irrigation, if you find (through testing using one of the appropriate analytical methods as described in subpart N of the proposed rule) that the estimate of the statistical threshold value (STV) of samples exceeds 410 colony forming units (CFU) of generic *E. coli* per 100 ml of water or that the geometric mean (GM) of samples exceeds 126 CFU of generic *E. coli* per 100 ml of water, you must either apply a time interval between last irrigation and harvest using a microbial die-off rate of 0.5 log per day and/or a time interval between harvest and end of storage using an appropriate microbial die-off or removal rates, including during activities such as commercial washing (or follow other options as described in § 112.44(c)) (proposed § 112.44(c), as amended by the supplemental proposed rule);

2) If you are using untreated BSA of animal origin it must be applied in a manner that does not contact covered produce during application and minimizes contact after application;

3) If you are using a treated BSA of animal origin (by a composting process in accordance with the requirements FDA proposed in § 112.54(c) to meet the microbial standard proposed in § 112.55(b)) and applying it in a manner that minimizes the potential for contact with covered produce during and after application, the minimum application interval is zero days (proposed § 112.56(a)(4)(i), as amended by the supplemental proposed rule);

4) At a minimum, if animals are allowed to graze or are used as working animals in fields where covered produce is grown, and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, the grower must take the following measures: (a) an adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed to ensure the safety of the harvested crop; and (b) if working animals are used in a growing area where a crop has been planted, measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce (proposed § 112.82); and

5) While taking into consideration that the produce safety rule neither authorizes any violations of the Endangered Species Act (16 U.S.C. 1531–1544) nor requires covered farms to take measures to exclude animals from outdoor growing areas or to destroy

animal habitat or otherwise clear farm borders around outdoor growing areas or drainages, if under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce, you must monitor those areas that are used for a covered activity for evidence of animal intrusion:

(1) As needed during the growing season based on:
    (i) The covered produce; and,
    (ii) The grower's observations and experience; and,
(2) Immediately prior to harvest.

If animal intrusion, as made evident by observation of significant quantities of animals, animal excreta or crop destruction via grazing occurs, the grower must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112 (proposed § 112.83(a) and (b) and, as proposed in the supplemental proposed rule, proposed § 112.84).

6) Comply with minimum-science based standards directed at:
   (1) Personnel Qualifications and Training, including by establishing requirements for training of personnel who handle (contact) covered produce or food-contact surfaces (proposed §§ 112.21 to 112.30) to ensure that personnel who operate or work for covered businesses are appropriately trained in food safety practices;
   (2) Worker Health and Hygiene (proposed §§ 112.31 to 112.33), including by establishing hygienic practices and other measures needed to prevent persons, including visitors, from contaminating produce with microorganisms of public health significance;
   (3) Growing, Harvesting, Packing, and Holding Activities, including by establishing that you take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, and ensure that food-packing material that is used in covered activities is clean and adequate for its intended use (proposed §§ 112.111 to 112.116);
   (4) Equipment, tools, and buildings, including equipment and tools that contact covered produce and instruments and controls (including equipment used in transport), buildings, domesticated animals in and around fully-enclosed buildings, pest control, and hand-washing and toilet facilities. The proposed standards include measures to prevent equipment, tools, and buildings, and inadequate sanitation from introducing known or reasonably foreseeable hazards into covered produce or food-contact surfaces (proposed §§ 112.121 to 112.140);
   (5) Sprouts, including by establishing measures that must be taken related to seeds or beans for sprouting (proposed § 112.141) and the growing, harvesting, packing, and holding of sprouts (proposed § 112.142). In addition, the proposed standards require that you test the growing environment for *Listeria* spp. or *L. monocytogenes* and that you test each production batch of spent irrigation water or sprouts for *E. coli* O157:H7 and *Salmonella* species and

take appropriate follow-up actions (proposed §§ 112.143, 112.144, 112.145, 112.146);

(6) Analytical methods, by establishing scientifically valid analytical methods for use to comply with relevant testing requirements (proposed §§ 112.151 and 112.152);

(7) Recordkeeping, including by establishing requirements for you to establish and keep certain records (proposed §§ 112.161 to 112.167);

(8) Variances, in which FDA proposed to set forth the procedures for requesting a variance by submitting to FDA a citizen petition using the process described in 21 CFR 10.30, specifically identifying the standard or standards from which the requesting entity is requesting a variance and identifying the specific growing conditions and science-based procedures or practices that would support a variance and FDA's review of such request (proposed §§ 112.171 to 112.182);

(9) Establishing compliance and enforcement provisions (proposed §§ 112.191 to 112.193)); and

(10) Withdrawal of Qualified Exemption, in which FDA proposed, among other provisions, procedures under which FDA may withdraw a qualified exemption applicable to a covered farm under one of two circumstances: (1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the farm that had received a qualified exemption (proposed § 112.201(a)) or (2) if FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at the farm (proposed § 112.201(b)); and procedures and circumstances under which FDA may reinstate a qualified exemption that is withdrawn (proposed § 112.213, as proposed in the supplemental proposed rule).

4.9 Mitigation

This section identifies mitigation measures that are intended to assist farmers affected by the rule with understanding and implementing compliance requirements associated with the rule (e.g., training, outreach, education).

A mitigating factor of particular importance is FDA's development of a compliance strategy that will be used for the implementation of the final rule. Education and technical assistance (including FDA-issued guidance documents) are the principal components of the compliance strategy. FDA believes that a comprehensive compliance strategy focused on education and technical assistance for farmers can help alleviate any uncertainty about requirements of any final rule, which, in turn, can help ensure that the provisions of the final rule are appropriately followed.

FDA has diligently been working toward this effort since FSMA was enacted. For example, in May 2014, FDA published the "Operational Strategy for Implementing the FDA Food Safety

Modernization Act (FSMA): Protecting Public Health by Strategic Implementation of Prevention-Oriented Food Safety Standards," which describes the guiding principles for implementing all aspects of FSMA, including produce safety standards (FDA, 2014a). In addition, FDA held a two-day public meeting entitled "FDA Food Safety Modernization Act: Focus on Implementation Strategy for Prevention-Oriented Food Safety Standards" on April 23-24, 2015, to present FDA's current implementation plans. The meeting was announced in the *Federal Register* on March 24, 2015, and included information on how to submit comments to a docket established to obtain comments on the FSMA implementation work plans (80 Fed. Reg. 15612).

With respect to education and technical assistance, FDA firmly believes that compliance cannot be effectively achieved based on FDA's efforts alone. Rather, FDA is building a network of partners that can assist with providing education and technical assistance to the farming community. This network involves collaboration with various institutions primarily via cooperative agreements, partnerships, and alliances—each of which is, in turn, described more fully below.

One of the key members of the network is the National Association of State Departments of Agriculture (NASDA), in which all 50 U.S. State Departments of Agriculture and the territories of American Samoa, Guam, Puerto Rico, and the U.S. Virgin Islands participate. In September 2014, FDA announced that a new cooperative agreement has been established between FDA and NASDA that will provide critical information on local produce growing, harvesting, packing, and holding, in an effort to assist states with aligning their requirements with the final rule (FDA, 2014c). Specifically, the cooperative agreement will "provide the funding and support necessary to determine the current foundation of state law, the resources needed by states to implement the produce safety rule, as well as develop a timeline for successful implementation once the rule is finalized" (FDA, 2014c).

While education and technical assistance would be available to everyone in the farming community who would be required to comply with any final rule, special focus has been put on growers and farmers with small operations. Accordingly, in January 2015, FDA announced that it has formed a collaborative partnership with the USDA's National Institute of Food and Agriculture (NIFA) to administer and manage the "National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program," a grant program that will provide funding so that small farm growers and owners receive adequate training, education, and technical assistance (FDA, 2015a).

The announcement also lists training grant application types that will be prioritized: "Priority will be given to those submitting grant applications to train owners and operators of small and medium-size farms; farmers just starting out in business; socially disadvantaged farmers; small food processors; small fruit and vegetable wholesalers; and farms that lack access to food safety training and other educational opportunities" (FDA, 2015a). The NIFA-FDA program will also award grants to establish one national coordination center that will coordinate the overall program and four regional centers that will reach out to the local communities. Moreover, the regional centers will coordinate with each other through the national coordination center which will further make certain that the information is provided throughout all areas of the country (FDA, 2015a). In addition to NIFA, FDA is partnering with multiple other organizations to assist with the

implementation of the final rule such as land grant University Cooperative Extension Services, community based organizations, and food safety professional organizations (FDA, 2015b).

Currently, FDA is also working with the Produce Safety Alliance (PSA) and the Sprout Safety Alliance (SSA) to develop training to help the farming community understand and comply with the final rule. The PSA, a collaborative effort with Cornell University, is currently developing training materials on the rule's requirements. The SSA, centered at the Illinois Institute of Technology, is also developing training materials specifically designed to assist sprout growers (FDA, 2015b). In addition to classroom training, FDA is collaborating with NASDA to develop a voluntary on-farm assessment program. These assessments are intended to be conducted before the compliance period is in effect to assist farmers in understanding what the rule requires before the mandatory compliance date arrives (FDA, 2015c).

Along with education and technical assistance, FDA-issued guidance documents round out the principal components of the compliance strategy. Section 419(e) of the FFDCA requires FDA to issue guidance documents to assist the farming community with rule compliance. FDA anticipates that the principle guidance document for compliance with the rule will be published in 2016, with other guidance documents following as resources allow. FDA will provide opportunity for public comment on the draft guidance documents so FDA can gain input from the affected community before issuing any final guidance.

5.0 Cumulative Impacts

5.1 Introduction

The Council on Environmental Quality (CEQ) Regulations for Implementing NEPA require a cumulative impact assessment within the decision-making process for proposed major Federal actions (see, *e.g.*, 40 CFR §§ 1508.7 and 1508.25(a)(2)). A cumulative impact is defined as "the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time" (40 CFR § 1508.7). CEQ's guidance for considering cumulative effects further states that NEPA documents "should compare the cumulative effects of multiple actions with appropriate national, regional, state, or community goals to determine whether the total effect is significant." (CEQ, 1997b).

Chapter 5.2 discusses the methodology used to evaluate potential cumulative impacts as compared with the environmental impacts that are addressed in Chapter 4. Chapter 5.2 also identifies Federal and non-Federal actions that are considered in this analysis because those actions may contribute to the aggregate and incremental impact of the proposed action when taken together across the nation and over a certain period of time.

5.2 Methodology for Analyzing Potential Cumulative Impacts

The timeframe for the analysis includes the past, the present, and the reasonably foreseeable future, which includes the compliance dates by which businesses potentially affected by the rule would be required to fulfill the requirements of the final rule. When we discuss actions that may occur within the reasonably foreseeable future, we refer to those actions that may be proposed by the lead federal agency or other agency actions, and which may be similar in nature, and contain similarities that provide a basis for evaluating the proposed actions together (see 40 CFR 1508.25(a)(3).[1] Reasonably foreseeable actions may also share common timing or geography, and the actions must have some influence on the resources affected by the EIS proposed action (CEQ, 1997b). As discussed in CEQ's *Effective Use of Programmatic NEPA Reviews guidance* (CEQ, 2014a), "[B]road Federal actions may be implemented over large geographic areas and/or a long time frame." As such, development programs that are proposed in the same region may be evaluated for cumulative effects if they have similar actions (*e.g.*, water withdrawals), and the analysis of those actions should reflect the major broad and general impacts that are relevant to the programmatic level of the NEPA document (*e.g.*, broad level of analysis) (CEQ, 2014a).

For the purposes of this analysis, FDA is considering the reasonably foreseeable future to extend beyond the compliance dates and into the implementation period when very small, small, and all other farms would be required to comply with the provisions of the final rule (compliance dates

[1] Relevant actions may be identified through during scoping or through consultation (*e.g.*, with other federal agencies, state agencies, Native American Indian Tribes).

are discussed within Chapter 2.1, Table 2.1-8). All provisions of the rule and other FSMA activities are considered to be fully implemented for this analysis.

The geographic scope of the analysis is the same as what is presented in Chapter 1.9. As part of the scoping process, FDA considered the potential environmental and related socioeconomic and public health impacts to regions within the United States (including all 50 states and the EIS geographical areas) (see Figure 1.7-4), as well as any environmental impacts that are caused by activities taken in response to the rule, if finalized, in areas within the geographical scope of the EIS (*e.g.*, transboundary impacts near the US borders with Canada/Mexico). Wherever feasible, due to the scale of the proposed action, FDA assesses potential impacts within regions or states, using qualitative information consistent with the scope of this EIS described in Chapter 1.9. The management decisions that a grower may take in order to comply with a final rule would be highly specific to the grower, the location (climate, water availability, soils and nutrient availability, commodity market, etc.), and any industry marketing agreements or local regulations that are being implemented. For the reasons we discussed in Chapter 1.9, we are considering environmental impacts in the EIS at the national, regional and, where feasible, state level.

FDA used the following steps to analyze potential cumulative impacts for this EIS:

1. Identify federal, state, or industry standards or practices that have relevance to the production of covered produce and that set guidelines that are important to reducing hazards associated with microbial contamination and associated outbreaks of foodborne illness;
2. Identify the participants included in the federal, state, or industry standards of relevance;
3. Identify potential other environmental, industry, or private actions nationwide that may contribute incremental adverse environmental impacts when added to those caused by the proposed action;
4. Identify the similarities and differences in the approach to establishing scientifically valid measures to reduce pathogens on fresh produce to enhance human health, the criteria established to achieve the desired result, and the time of issuance of the various standards.
    a. Examine for similar regulatory or industry programs that place requirements on the same affected community[2];
    b. Examine for complementary program elements that have already established measures similar to the PS PR; and,
    c. Compare to see if the PS PR is more or less stringent than existing standards.

FDA has determined that domestic farms and farm-mixed type facilities that grow covered produce[3] would incur costs as a result of complying with a final rule (FDA, 2013b and 2014b). In addition, the farmer may make some management decisions in order to come into compliance with,

[2] For example, there may be more than a hundred different types of State and industry-driven marketing agreements nationwide that may have various requirements related to provisions proposed in the PS PR. FDA looked at a few representative examples (*e.g.*, CA LGMA or T-GAPs) as a means of comparison.
[3] Covered produce is defined in Chapter 1.6 and 21 CFR proposed § 112.1,

or to potentially avoid being subject to, a final rule (management decisions are discussed in more detail in Chapters 1.9, 2.1, and throughout Chapter 4). These management decisions may result in added costs to operate the farm, and potentially may adversely impact the environment. Potential environmental effects may extend throughout a region if enough growers make changes at a local scale to influence a wider geographic area (*e.g.*, groundwater withdrawals). Public health (including low income, minority, and Native American Indian Tribes) may also be affected both adversely and beneficially as a result of the proposed action. It is important to note that this analysis also includes those provisions that were identified as not being "potentially significant provisions"[4] that could result in potential significant impacts to the environment (discussed in Chapter 2.2). Although FDA determined in Chapter 2.2 that these provisions (subparts C, K, L, N, O, P, Q, and R) would not individually reasonably result in significant adverse environmental consequences, they may cumulatively result in significant adverse environmental impacts, particularly in terms of management decisions made as a result of potential added costs to farms affected by the rule.

The conditions that affect farms nationally are discussed throughout the EIS. Persistent environmental conditions that have changed how agricultural communities operate and that continue to force farmers to adapt to these changing conditions (*e.g.*, types of crops produced, how they irrigate crops) are discussed at the end of Chapter 1.9. Current baseline conditions that are relevant to specific proposed provisions are discussed in Chapter 2.1. Background environmental conditions (*e.g.*, health of the water, soil, air, and industry practices such as how and where manure is generated) are discussed throughout Chapter 3 and in Appendices B and C. Conditions relative to the No Action Alternative and to certain potential management decisions are discussed throughout Chapter 4. The aggregate of these conditions represents the affected environment, which is also relevant to this cumulative effects analysis.

5.3 Federal and Non-Federal Actions Relevant to the Cumulative Impacts Analysis

5.3.1 Related FSMA Actions

The following FDA NEPA documents were consulted because they directly relate to other FSMA actions. Categorical Exclusions are defined as categories of actions which do not individually or cumulatively have a significant effect on the human environment and, therefore, would not contribute to any potentially significant effects within this cumulative impacts analysis (40 CFR § 1508.4). For each of the related FSMA actions listed here, FDA determined that these actions qualify for a categorical exclusion from the need to prepare an environmental assessment under 21 CFR 25.30(h), and that no extraordinary circumstances exist that would require the preparation of an environmental assessment or an environmental impact statement.

[4] Potentially significant provisions are defined in Chapter 1.2.

FSMA Intentional Adulteration Proposed Rule
November 14, 2013, Categorical Exclusion Evaluation (FDA, 2013d): The identified impacts include beneficial impacts to Human Health and Safety, as well as insignificant Ecological and Biological impacts. The proposed rule mentions, but does not require, the use of broad mitigation strategies (*i.e.*, fencing) to assist with protection of food from intentional adulteration. Such broad mitigation strategies, which serve as foundational actions or procedures that improve a facility's overall defense against intentional contamination caused by acts of terrorism, are already largely in use or would be implemented at largely industrial locations.

FSMA Preventive Controls for Human Food (PC HF)
June 21, 2011 (FDA, 2011c) and (Supplemental) August 29, 2014, Categorical Exclusion Evaluation (FDA, 2014d): The PC HF requires that the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under Section 402 or misbranded under Section 403(w) of the FFDCA. No extraordinary circumstances exist that would require the preparation of an environmental assessment or an environmental impact statement, although beneficial impacts on human health would be anticipated.

FSMA Proposed Rule for Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals
August 25, 2011, Categorical Exclusion Evaluation (FDA, 2011d): The FSVP requires good importing practices for food for humans and animals, requiring hazard analysis and supplier verification. This rule is related to imports, creates no new requirements for produce, and only requires verification that proposed 21 CFR part 112 regulations have been followed.

FSMA Third Party Accreditation
September 1, 2011, Categorical Exclusion Evaluation (FDA, 2011e): This proposed rule would establish a system for the recognition of foreign government agencies or private companies that would accredit third-party auditors of foreign food facilities. These auditors would conduct food safety audits and issue certifications that FDA may use in deciding whether to admit certain imported food into the U.S. that the agency has determined poses a food safety risk.

FSMA Sanitary Transportation of Human and Animal Food Proposed Rule (ST PR)
November 22, 2011, Categorical Exclusion Evaluation (FDA, 2011f): While no extraordinary circumstances exist that would require the preparation of an environmental assessment or an environmental impact statement, we note that FDA considers this type of action to be part of a class of actions that will result in beneficial impacts to human health and safety.

5.3.2 Other Past, Present, and Reasonably Foreseeable Future Actions

Table 5.3-1 includes other federal and non-federal actions that could have affected or could affect growers of covered produce. Table 5.3-1 also lists similar federal and state/private efforts to manage pathogen transport on fresh produce commodities. In addition, the table includes one

major subsidy elimination action related to a high-value crop that could be grown on farms with small tracts of land available. Furthermore, the table includes sustainable conservation practices and measures that work in tandem with efforts between industry and the government to support conservation on the farm and to build a sustainable system where farm production can supportively coincide with wildlife and habitat management efforts. More specific requirements on some of these programs are found in Chapter 2.1, Table 2.1-1.

Table 5.3-1. Comparable Federal and non-Federal actions

Comparable Program	Brief Description	Relevant Standards	Past, Present, and Future Outcomes
FDA Guidance to Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (the GAPs Guide)	Contains voluntary recommendations that growers and packers can take to minimize contamination in their operations, and includes practices associated with the growing, harvesting, packing and holding of fresh produce.	The GAPs Guide provides recommendations for: - Agricultural water - Manure - Worker health & hygiene - Sanitary facilities - Field sanitation - Packing facility sanitation - transportation	Established in 1998, the GAPs Guide is the basis for the USDA AMS GAP&GHP audit program (see Chapter 2.1)
USDA AMS GAP&GHP audit program	Provides voluntary independent audits of produce that are focused on best agricultural practices to verify that fruits and vegetables are produced, packed, handled, and stored in the safest manner possible to minimize risks of microbial contamination	- The GAP&GHP audits verify adherence to the recommendations made in the GAPs Guide and industry recognized food safety practices.	Established in 2006
USDA organic regulations 7 CFR Part 205	National standards for organically produced agricultural products; restrictions include the national list of allowed and prohibited substances. Includes timing restrictions for using untreated manure, and standards for composting.	- Pre-harvest and post-harvest water standards - Untreated and treated BSAs of animal origin	Has existed since 1990. Participants who agree to adhere to the requirements can market their product as Certified Organic.

Comparable Program	Brief Description	Relevant Standards	Past, Present, and Future Outcomes
USDA-NRCS Conservation Technical and Financial Assistance	Provides the agriculture industry with guidance for applying conservation technology on the land. Standards for those voluntarily applying conservation practices are issued in the National Handbook of Conservation Practices and are updated through notices. [5]	- May be used on a voluntary basis by growers of covered produce.	Has existed since 1990. Protects soil, water, and enhances potential for profitability.
The Fair and Equitable Tobacco Reform Act of 2004	The Tobacco Transition Payment Program (TTPP), also called the "tobacco buy-out," helps tobacco quota holders and producers transition to the free market.	- None (relevancy may include if former tobacco growers switch to growing covered produce, which has historically occurred in States, *e.g.*, Maryland, where the tobacco transition program caused a shift in a small portion of the growing industry).	Payments began in 2005 and ended in 2014.
Tomato Good Agricultural Practices (T-GAPs) and Best Management Practices Manual (BMP)	Mandatory program in Florida (voluntary elsewhere) for growers of tomatoes, designed to prevent and reduce microbial contamination, and must be followed in the production, handling, packing, distributing, transporting, selling and serving of the product.	- Pre-harvest and post-harvest water standards - Agricultural / irrigation water quality requirements - Worker health & hygiene - Application of manure (raw and composted) - Equipment - Recordkeeping - Pest management and animal exclusion	Florida's program was formed in 2007
Leafy Greens Marketing Agreements	Voluntary program for growers of edible leafy vegetable produce in California and Arizona.	- Pre-harvest and post-harvest water standards - Untreated and treated BSAs of animal origin - Wild Animals	CA LGMA was formed in 2007. AZ LGMA was formed in 2007.
Industry-Wide Food Safety Standards for Fresh Mushroom Growing, Harvesting, and Shipping	Voluntary program for growers of edible fungi throughout the U.S.	- Pre-harvest and post-harvest water standards - Untreated and treated BSAs of animal origin - Wild Animals	Went into effect in 2008.

[5] More information on NRCS Conservation Practice Standards may be found at the following Web site: http://www.nrcs.usda.gov/wps/portal/nrcs/detailfull/national/technical/references/?cid=nrcsdev11_001020.

Comparable Program	Brief Description	Relevant Standards	Past, Present, and Future Outcomes
FDA Draft Guidance for Industry: Guide to minimize food safety hazards of tomatoes	Guidelines provide recommended food safety practices that are intended to minimize the microbiological hazards associated with fresh and fresh-cut tomato products.	- Agricultural water - Untreated and treated manure - Pest management - Worker health & hygiene and training - Recordkeeping - Packing, handling, and holding activities	Issued in 2009
FDA Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons	Recommends practices to minimize the microbial food safety hazards of their products throughout the entire melon supply chain	- Recordkeeping - Equipment cleaning and sanitation - Pest management - Worker health & hygiene and training - Agricultural water	Issued in 2009
FDA Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens	Recommends practices to minimize the microbial food safety hazards of products throughout the entire leafy greens supply chain	- Recordkeeping - Equipment cleaning and sanitation - Pest management - Worker health & hygiene and training - Agricultural water	Issued in 2009
California cantaloupe program	State-specific, commodity specific voluntary program; includes requirements for a Food Safety Compliance and Implementation Plan, water testing, worker safety, hygiene, and training, and environmental analysis (including animal intrusion and flooding) and documentation of soil amendments.	- Pre-harvest and post-harvest water standards - Untreated and treated BSAs of animal origin - Wild Animals	Went into effect in 2012.
State specific agricultural water quality standards and nutrient management standards	State laws and EPA delegated CWA and SDWA authority.	- Pre-harvest and post-harvest water standards	Varies.

Comparable Program	Brief Description	Relevant Standards	Past, Present, and Future Outcomes
FSMA Preventive Controls for Human Food Final Rule (PC HF FR)	Regulates food processing facilities (*e.g.*, food manufacturing facilities and farm mixed-type facilities), and includes (1) New requirements for hazard analysis and risk-based preventive controls and (2) Revisions to existing CGMP requirements.	- Health and Hygiene - Record-Keeping	Finalized in September 2015, with compliance dates ranging from September 2016 – September 2018 depending on business size.

In addition to Table 5.3-1, there are other non-specific actions and impacts that are occurring nationwide that, when taken together with the FDA's proposed action, could result in cumulative effects to growers of covered produce.

Non-specific actions

Oil and gas exploration and development. Federal oil and gas lease surface operations are managed by the Bureau of Land Management (BLM) in cooperation with the appropriate Federal surface management agency (federal land owner) or non-Federal surface owner. The BLM is responsible for ensuring compliance with NEPA for oil and gas exploration on Federal lands nationwide. In support of its environmental responsibilities, the agency has developed a Gold Book that includes best management practices for minimizing and mitigating adverse environmental impacts. Nevertheless, significant adverse effects to natural resources are documented annually as a result of exploration and development.

Residential and commercial development. The U.S. Department of Housing and Urban Development (HUD) is the federal agency responsible for national policy and programs that address America's housing needs. HUD reported in September of 2014 that purchases of new home sales climbed 18.0 percent from a month earlier to a seasonally adjusted annual rate of 504,000 in August (HUD, 2014). [6] Since publication of the Draft EIS, HUD's most recent housing needs report (reported through June 2015) shows new home sales were at a seasonally adjusted annual rate of 482,000, which is 6.8 percent below the May 2015 new home sales rate of 517,000, and 4.4 percent below the August 2014 reported rate. The HUD data demonstrates slight variations, both up and down, in new home sales from a year ago (HUD, 2015).

The National Association of Realtors reported that for the year 2013, new completions (new development) resulted in a net gain of 33 million square feet of office property, and that number grew by 18.4 million square feet for 2014. For industrial property, there was 115.7 million square feet developed within the first nine months of 2013, and another 81 million square feet of new construction were added in 2014.

While some of this development occurs on previously disturbed land, other development (unspecified) would require clearing vegetation and impacts to surface waters and wetlands.

[6] This represents new construction; there are separate statistics on sales of existing homes.

Groundwater drawdown. Although this is addressed in Chapter 3.1 and in Chapter 4, the USGS reports that groundwater use has increased markedly since the 1950s (USGS, 2013b). There are several geographical areas where large-scale groundwater depletion is evident over agricultural areas with a high percentage of the covered farms (Figure 3.1-23). Significant dewatering is evident over the Central, Coachella and Death Valleys of California; Alluvial Basins of Arizona; and the Columbia Plateau in southeastern Washington and northeastern Oregon. Agricultural uses remain a primary cause of groundwater withdrawals in many regions.[7]

Land subsidence. Although this is addressed in Chapter 3.3 and in Chapter 4, land subsidence will continue to be exacerbated by a number of factors including agriculture and continued commercial and residential development. The USGS reports that land subsidence in the U.S. has directly and adversely impacted more than 17,000 square miles of land/soils in 45 States; this is an area roughly the size of Vermont and New Hampshire combined (USGS, 2000). The principal causes are aquifer system compaction, drainage of organic soils, underground mining, hydrocompaction, natural compaction, sinkholes, and thawing permafrost (National Research Council, 1991). For the purpose of this EIS, and in accordance with USGS reports, land subsidence as a baseline condition is considered an ongoing significant adverse environmental impact.

Climate change. The Intergovernmental Panel on Climate Change (2014) released a report that highlights the changes in worldwide climate and the impacts on human and natural systems. The changing climate has been indicative of an overall decrease in cold temperature regions, an increase in warm temperature extremes (includes the arid Western U.S.), a projection for more intense weather conditions and extreme precipitation events, to name a few. The report further indicates that rural areas the world over are expected to experience severe impacts related to water availability and food security, which in turn is anticipated to directly affect agricultural income. One distinct effect includes a shift in where food crops are grown worldwide.

5.4 Federal and Non-Federal Action Descriptions

This section provides descriptions of the actions listed in Table 5.3-1 as a means of comparing these actions to FDA's proposed action.

FDA Guidance to Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables
FDA Draft Guidance: Guide to Minimize Microbial Food Safety Hazards of Tomatoes
FDA Draft Guidance: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens
FDA Draft Guidance: Guide to Minimize Microbial Food Safety Hazards of Melons
And USDA AMS GAP&GHP audit program

[7] The USGS has a dedicated Web site regarding water science in California that publishes regular data on water quality and supply, climatic stress (including the present drought conditions), and monitoring data. Water availability in California is a current and ongoing problem, particularly as it pertains to impacts to agriculture. More information on drought in California and its resulting effects is available at http://ca.water.usgs.gov/index.html.

As discussed in Chapter 1.9, in 1998, FDA issued its *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* ("1998 Guide" or "FDA's 1998 Guide") (FDA, 1998).[8] In 2002, the New Jersey Department of Agriculture petitioned USDA AMS to implement an audit-based program to verify conformance with the 1998 Guide. This led to the creation of USDA AMS's GAP&GHP audit program (USDA AMS, 2006). The audit program offers voluntary independent audits of produce that are focused on best agricultural practices to verify that fruits and vegetables are produced, packed, handled, and stored in the safest manner possible to minimize risks of microbial contamination. The audits confirm adherence to FDA's recommendations made in its 1998 Guide as well as other industry-recognized food safety practices (USDA AMS, 2013b).

As a result of commodity-specific outbreaks of foodborne illnesses, FDA published commodity-specific food safety draft guidelines for the melon supply chain, leafy greens, and fresh tomatoes. The major elements of these draft guidance documents that are relevant to the PS PR are listed in Table 5.3-1. Essentially, these documents have provided growers of fresh produce with preventive measures that farms may take to minimize food safety hazards. Some of these recommendations have been adopted (in whole or part) by industry marketing groups within which participants of the marketing agreements managed by those groups must follow certain food safety guidelines. FDA guidance represents a wholly beneficial influence for food safety throughout much of the fresh produce market.

USDA organic regulations (7 CFR Part 205) – USDA organic regulations, as detailed in Chapter 1.4 and elsewhere throughout the EIS, are a program established for a certain consumer market with the desire to reduce the amount of artificial inputs such as pesticides, herbicides, and artificial fertilizer in foods. The program does not have restrictions on the microbial content of agricultural water, although it does regulate or restrict the chemical additives to such water. The program also places restrictions on certain types of BSAs of animal origin with respect to application to harvest intervals (for untreated manure) based on organic crop production practices.

USDA-NRCS Conservation Technical and Financial Assistance – NRCS conservation planning assistance is available (generally through cost-share programs and technical assistance) on a voluntary basis to producers.[9]

Fair and Equitable Tobacco Reform Act of 2004 (FETRA) – A component of the Jobs Creation Act and instituted by USDA by the Tobacco Transitional Payment Program, this act created a voluntary program to gradually phase out subsidy programs that paid tobacco growers incentives, with payments ending in 2014. Because tobacco farming is a high-value crop, many farms with limited acreage relied on growing it exclusively or as a predominate cash crop. In some tobacco regions, one possible management decision was to cease farming altogether at the beginning of

[8] Since the document was issued as guidance and not as a regulation, it does not have the force and effect of law and therefore does not contain enforceable requirements.

[9] Conservation technical and financial assistance, including Conservation Practice Standards, is not a regulatory program and does not have the force and effect of law.

the phase-out program; the response from many regions or States' growers was to convert to other high value crops, including produce.

Florida (and other) tomato food safety audit protocol standards and verification – The USCB reports that roughly 289,000 acres were harvested in the U.S. for fresh tomato production in 2010 (USCB, 2012). Leading states in tomato production include Florida, California, Georgia, Indiana, Ohio, and Tennessee (USCB, 2012), but many states grow tomatoes primarily for processing. Florida is the top producer of fresh tomatoes in the U.S. (approximately 42 percent by weight), followed by California (approximately 28 percent by weight) (Jones, 2014). The Florida program is mandatory for all tomato growers; however, other states have voluntary programs, but with similar food safety standards. The Florida Department of Agriculture and Consumer Services (DACS) has published a Tomato Best Practices Manual that includes Tomato Good Agricultural Practices (T-GAPs) and Tomato Best Management Practices (T-BMP)[10]. T-GAP (a mandatory program for Florida tomato growers) prohibits tomato fields from being located where drainage or drift from an animal operation or any other source of contamination can be received. Domestic animals and livestock are prohibited from tomato growing fields during the growing season and during harvest. Wild animal intrusion is to be minimized to the degree possible by methods identified by wildlife experts (there were no observed requirements for excluding wild animals). There must be a pest control program environmental review and monitoring review.

In terms of agricultural water, irrigation water for tomato production in Florida must meet the following requirements:

- Water used for irrigation must meet EPA's standard for *E. coli* in recreational waters,[11] which is a standard that is similar to the PS PR, but may be considered more stringent because FDA's proposed numeric standard allows for steps to account for post-irrigation microbial die-off and/or removal. Wells must be properly constructed and maintained to prevent contamination, and approved water treatments may be used to bring water into compliance with the standards in 40 CFR Part 131.4(c) except that treated water must not be in conflict with local requirements. Furthermore, foliar application at the time of harvest must meet microbial standards for potable water.
- Water used for washing tomatoes after harvest must meet microbial standards for potable water in 40 CFR Part 141.63 (*i.e.*, a zero, non-detectible reading or count of *E. coli*), and surface water that is not treated may not be used.

In terms of soil amendments, only properly composted manure is allowed for use in tomato fields and greenhouses in the Florida program. Untreated or raw manure is prohibited for application to tomato growing areas. Proper treatment requires records of composition, dates of treatment, methods utilized, application dates and letter of guarantee, Certificate of Analysis (COA) or any

[10] Exemptions from T-GAP and T-BMP are provided for growers selling direct to consumers on the farm premises, as "U-pick," or at local farmers markets or roadside stands, provided the amount of tomato product does not exceed two 25-pound boxes per customer.

[11] Specifically the EPA standard is as follows: Culturable *E. coli* at a GM of 126 CFU per 100 ml and an STV of 410 CFU per 100 ml measured using EPA Method 1603, or any other equivalent method that measures culturable *E. coli*.

test results or verification data demonstrating compliance with process or microbial standards to be documented. There is no single standard for "proper treatment," as an auditor reviews the amendment use documents and records for compliance with prevailing national or local established composting or heat treatment standards or guidelines.

California and Arizona leafy greens marketing agreements (example of marketing agreements that are in place presently and have some standards that are similar to the PS PR) – Due to the popularity of fresh greens and in response to recent food safety concerns, these voluntary programs were enacted for their members to provide several standards that improve food safety for consumers of their products. Recalls cost the industry a considerable amount of capital, and subsequent carryover due to delayed consumer response to resume purchasing those products again had economic impacts on the growers of fresh greens.

There are three principal regions of the U.S. where leafy green fresh produce is grown for commercial distribution throughout the country: (1) Winter – November through March – the desert region of southern California and Arizona; (2) Spring and Fall – the San Joaquin Valley of California; and (3) Summer (late Spring and early Fall) – April through late October/early November – the central coast region of California (California Leafy Green Handler Marketing Board, 2012). Although this is but one distinct commodity, the states involved in the LGMAs account for the vast majority of this class of produce grown in the U.S. for consumer consumption.

The western grower LGMAs are voluntary programs with high participation rates (approximately 99 percent of California commercial leafy greens growers and 85 percent of Arizona's leafy greens growers). Standards under the LGMAs are mandatory for those who choose to participate. However, leafy greens (edible leaves and shoots from lettuces, cabbages, mesclun, spinach, and similar plants) represent only a subset of the types of covered produce, albeit one of the most popular produce products currently commonly in use year-round. Therefore, the area of impact does not include the entire covered produce grower community, which includes other commodities and States.

These LGMAs include required microbial agricultural water standards for both irrigation (pre-harvest) and holding and packing (post-harvest) processes. The standards are as follows:

- Pre-harvest water that contacts edible portions of crop (*e.g.*, overhead irrigation, pesticide/fungicide applications) must be analyzed for generic *E. coli*; and acceptable levels are no more than 126 MPN/100ml (GM of five samples) and no more than 235 MPN/100ml (all single samples), which is more stringent than FDA's PS PR.
- Pre-harvest water where edible portions of crop are not contacted by water (*e.g.*, furrow or drip irrigation of above-surface crops, and dust abatement water) must be analyzed for generic *E. coli*; and acceptable levels are no more than 126 MPN/100ml (GM of five samples) and no more than 576 MPN/100ml (all single samples), which is more stringent as compared to the PS PR numeric standard when one considers the flexibility FDA provides for post-irrigation microbial die-off and/or removal.
- Postharvest water (with direct produce contact, *e.g.*, re-hydration, core in field) must be analyzed for generic *E. coli*; and the acceptable level is zero ("negative" or "below

detection limits"/100 ml) or must be treated after contact, which is the similar to the PS PR proposed standard for agricultural water that is not used for irrigation.

These LGMAs also include prescribed restrictions on usage of BSAs of animal origin:

- Untreated or "raw" manure cannot be used in edible crop production, which is similar to the PS PR.
- For previously treated fields used for other crops during the prior growing season, a 12-month (1 year) waiting period is required before planting any variety of leafy green crops for human consumption, which is more stringent than the PS PR.
- Treated (composted) BSAs of animal origin (including non-validated heat-processed manure) may be used only if microbe levels are below corresponding action level numbers, then an application interval of at least 45 days before harvest must be observed, which is more stringent than the PS PR.
- Thermally processed treated (heated/treated) soil amendments, for validated process, are allowed with no required application time interval before harvest, which is similar to the PS PR.

Industry-wide food safety standards for fresh mushroom growing, harvesting, and shipping (example of marketing agreements that are in place presently and have some standards that are similar to the PS PR) – Developed by the American Mushroom Institute (AMI) and Pennsylvania State University in 2008, the Mushroom Good Agricultural Practices Program provides a set of food-safety standards that mushroom growers can voluntarily follow to ensure the safety of fresh mushrooms. Updated in 2010, the standards are documented in the "Industry-Wide Food Safety Standards for Fresh Mushroom Growing, Harvesting, and Shipping" (commonly referred to as the MGAP standards).

Similar to the PS PR, the MGAP standards are comprehensive in that they cover a wide variety of topics such as water, soil amendments, animal intrusion, personnel training, hygiene, and sanitation of equipment/buildings.

The MGAP's irrigation numeric water standard is more stringent in that it requires mushroom irrigation water to meet EPA's microbial standards for drinking water (no detectible generic *E. coli* within 100 ml of water).

Other MGAP standards to note include those regarding soil amendments and pest control. The MGAP standards regarding soil amendments are written to relate to the industry's commodity-specific growing medium for mushrooms, known as substrate. Mushroom substrate typically includes a variety of agricultural materials, such as straw, hay, and manure (Penn State, 2008). Since manure is a common component of the mushroom substrate, the PS PR's standards regarding untreated and treated BSAs of animal origin are relevant. In the mushroom industry, the first step to growing mushrooms is preparing the substrate, a process also frequently referred to as mushroom composting. During this process, substrate is created during a two-phase heating process (Penn State, 2008). Therefore, if the substrate undergoes this physical (thermal) treatment

process, it would likely fall under the proposed § 112.54(a), and no application interval is necessary.

In addition, although the high temperatures achieved during mushroom substrate preparation substantially reduce levels of harmful microorganisms, the MGAP standards recognize that there is still the potential for cross-contamination of non-substrate materials and mushrooms with unpasteurized substrate. Therefore, the MGAP standards require that those who choose to comply with the MGAP receive and store raw manure and unpasteurized substrate *as far away as possible* from receiving areas where harvest containers, packaging materials, and other sanitary supplies are received or where mushrooms are shipped.

With regard to wild animals, the MGAP standard is exclusion of pests (includes insects, rodents, and birds) using safe and effective procedures such as minimizing pest entry points, using EPA-approved pesticides according to state and/or federal regulations, and setting traps.

California cantaloupe program (example of marketing agreements that are in place presently and have some standards that are similar to the PS PR) - Program requirements and controls for the California Cantaloupe program participants include completing a Food Safety Compliance and Implementation Plan; water testing for irrigation and packing water; worker safety, hygiene, and training; environmental analysis including identification of animal intrusion and contamination from flooding from animal feeding operations; and documentation of soil amendments including compost and fertilizer.

The Cantaloupe program has separate standards for pre-harvest *foliar* application – 126 MPN mean/235 MPN maximum (*e.g.*, overhead spray); and *non-foliar* irrigation water application (*e.g.*, drip or trickle) – 126 MPN mean/576 MPN maximum; and different test frequencies depending on source waters. The numeric standards for cantaloupe are considered more stringent than what is proposed in the PS PR because there is no flexibility added to allow for pathogen die-off, such as what FDA proposes (CCAB, 2013).

The California Cantaloupe program allows the use of treated soil amendments (composted manure) but has several restrictions: (1) a certificate from the producer or seller must be obtained and retained to verify the validated methods to ensure pathogen reduction, (2) the compost must be tested for target organisms (including fecal coliform bacteria, *Salmonella*, and STEC), and (3) an application interval of greater than 45 days prior to harvest. The program completely disallows the use of raw manure. These restrictions are more stringent than what is proposed in the PS PR.

The Cantaloupe program also has a standard for animal intrusion, and contamination from flooding that interfaces with animal feeding operations (where manure is present or stockpiled). However, there is no preclusion from domesticated animal grazing (which would not occur during the growing season) (CCAB, 2013).

State-specific agricultural water quality standards and nutrient management standards - Very few states have set microbial standards for irrigation water (examples of states that have established such standards are Alaska, Colorado, Delaware, and Oregon) outside of commodity-

specific marketing agreements with USDA AMS. There are a number of states (*e.g.*, Colorado and Utah) that have state laws with salinity and chemical standards for agricultural water, and some that have some guidelines and possible restrictions on the use of pesticides for agricultural irrigation water. Such standards are state-specific. Conversely, all states have drinking water quality standards and for the most part, these standards are based upon EPA's recreational water quality criteria.[12] Other states may rely on guidance, such as best practices for growing produce relative to where animal operations are managed.

Conversely, a larger number of states regulate the runoff to *receiving* streams from facility activities, but do not have standards on the irrigation water applied to crops themselves. For example, 45 states require farms to prepare nutrient management plans, which are in part designed to better manage nutrient inputs (*e.g.*, treated or untreated manure or chemical fertilizers), in order to help reduce nutrient runoff into receiving surface waters that would otherwise impact State TMDL compliance (see Chapter 3.1). In addition, all states have NPDES requirements that are based on EPA requirements. Under NPDES, most facilities that discharge pollutants from any point source into waters of the United States (regulated waters) are required to obtain a permit. Such permitted activities or businesses that may be covered by the rule include CAFOs or AFOs that manage livestock and poultry operations (EPA, 2014o) (see Chapters 3.1.2, 3.4.2, 3.4.3.5, and Chapter 4.1).[13] Approximately 2,829 potentially covered farms manage livestock or poultry operations and also grow covered produce; some subset of this number of covered farms may operate under a NPDES permit.

Many water quality issues and related standards are state-specific and include regulatory drivers such as legal issues concerning water rights, clean streams (discharges and non-point contributions to receiving waters), subsurface discharge for aquifer recharge, public health in terms of drinking water, anti-degradation of water for wildlife and public health concerns, and soil quality (factors that could degrade fertility including salinity and target chronic toxins).

FSMA Preventive Controls for Human Food (PC HF) - This FDA final rule requires registered food processing facilities (including farm mixed-type facilities), with some exceptions, to complete a hazard analysis, and apply preventive controls that include process controls, food allergen controls, sanitation controls, and a recall plan.

Very small businesses (less than $1 million in total annual sales of human food) have modified requirements. Such businesses may be required to comply with the requirements of the PS PR if they are farm mixed-type facilities. The PC HF will be phased in over one to three years depending on sales amounts, such that there would be three years for very small businesses, two years for small businesses with fewer than 500 employees, and one year for businesses that are not small or very small.

[12] While the EPA criteria are not specific to irrigation water, it may be that some states rely on the criteria respective of agricultural water for food crops.
[13] The specific Web site that discusses NPDES regulations for CAFOs/AFOs is found at http://water.epa.gov/polwaste/npdes/afo/CAFO-Regulations.cfm.

There are no standards for agricultural water, BSAs of animal origin, or domesticated and wild animals in growing areas specified in the PC HF. However, certain farm mixed-type facilities may rely on compliance with the PS PR provisions for control of microbial hazards in incoming ingredients.

Other parts of the PC HF that are similar to the PS PR include hand washing, cleaning and sanitization of machinery or equipment, and recordkeeping. However, these requirements are not additive (if satisfying one rule, both are by definition satisfied; moreover, record-keeping does not need to be duplicative).

There is a potential for certain businesses to be required to comply with both the PC HF and the PS PR. Certain farms that would be subject to the PS PR (including based on annual sales) that also conduct additional processing or manufacturing may also be subject to the PC HF rule for those activities. Such farms would be considered large businesses under the PS PR: A farm mixed-type facility would need to have sales of $1 million or more annually of human food before they could become subject to the full requirements of both rules; otherwise, such a facility would have modified requirements under the PC HF rule as a very small business.

5.5 Analysis and Conclusions

A summary of the potential environmental impacts for potentially significant provisions is provided in Chapter 4.7. As discussed in Chapter 4.7, unlike with standards directed at specific potential routes of pathogen introduction (such as for potentially significant provisions), subpart A of the PS PR establishes the level of sales above which a farm growing covered produce would be subject to all the provisions of the rule. Under subpart A, covered farms must comply with the provisions of the rule, including through the use of the management decisions described in Chapters 4.2 to 4.6, or they must switch to crops that are not covered by the proposed rule. In other words, if a farm is covered by the rule as established in proposed subpart A, then all the potential environmental impacts associated with management decisions and the alternatives which the agency believes will best "fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors" (CEQ, 1981) are also expected to occur.

The potential environmental impacts associated with those management decisions and alternatives is summarized in Chapter 4.7.[14] This summary of potential environmental impacts is subdivided by resource component (*e.g.*, water resources, air quality).

This cumulative impacts analysis also looks at those resource components and assesses them together with the programs and actions discussed in the previous sections of this chapter. This assessment represents the "cumulative impact" on the environment that results from the incremental impact of FDA's proposed action when added to other past, present, and reasonably foreseeable future actions presented above. Therefore, the potential environmental impacts

[14] See the heading for Subpart A: General Provisions (Scope of Coverage of the Proposed Rule); includes impacts related to the cumulative effects of each proposed standard assessed together).

discussed below, in some cases, may be more severe than the impacts that were assessed in Chapter 4.7.

Water Resources – The range of potential cumulative impacts nationwide are anticipated to range from not significant to significant adverse depending on the alternative that FDA may select. The potential cumulative impacts are described in more detail in the following statements.

Water availability

Groundwater withdrawals, as discussed in Chapter 3.1.3.11 and Chapter 4.1, continue to have significant adverse effects on the amount of water in aquifers that is available for agricultural use, human consumption, and industrial and commercial use across the nation. According to USGS data and 2005 estimates, 37 percent of total U.S. groundwater withdrawals were for irrigation water, and an additional 2.6 percent covers other agricultural waters. Thermoelectric power accounts for 41.5 percent of withdrawals, domestic users for 8.5 percent, other publicly supplied users for 5.4 percent, and industrial users account for 5 percent. Trends presented in Chapter 3 show that the amount of groundwater withdrawals continues to rise in both number of users and volume of water. Water conservation practices (*e.g.*, drip and low-flow irrigation) continue to gain in popularity, but there are no statistical data that show there is a total measurable effect on the amount of groundwater withdrawals nationwide.[15] Nationwide, the availability of groundwater is a condition that continues to worsen, and these conditions may be exacerbated in regions where drought-related climate change effects are experienced the most.

Significant current and ongoing adverse environmental impacts, such as reduced water availability, water-table declines, and soil subsidence, resulting from groundwater withdrawals are presently experienced in regions B, C, D, I, J, and U, as well as corresponding regions in the northeastern and northcentral reaches of Mexico that share an aquifer with regions D, I, or J (compare Figure 1.7-4 with Figures 3.1-12 and 3.1-13). These impacts are already occurring absent of any final rule. Any action (personal, federal, state, local, etc.) in regions B, C, D, I, J, and U that would cause a farmer or any entity to draw from groundwater instead of surface water could exacerbate the current environmental conditions, generally. The analysis in Chapter 4.7 found that under the preferred alternative (subpart E Alternative IV-a, and subpart A), FDA does not anticipate that a final rule would result in the management decision that farms on a regional or national scale would switch to groundwater sources. However, some limited number of farms may switch to groundwater sources and, therefore, would exacerbate the significant impacts currently occurring to groundwater sources. When one considers the potential impact of the rule along with an expectation of growing water demand for residential, commercial, and industrial development and the continued oil and gas exploration that occurs nationwide (consumes large amounts of water) (see Chapter 3.1), long-term effects to water availability—particularly in regions B, C, D, I, J, and U, as well as corresponding regions in the northeastern and northcentral reaches of Mexico that

[15] While it is plausible that water conservation practices have a beneficial impact, the impacts have not been widely studied. It is possible that if water is being spared at one part of the farm for irrigation, it may be used in more volume for other parts (potentially non-covered crops). In many areas across the U.S. it is impossible for the government to track exactly how much water is being used by growers because the water is pulled directly from groundwater or surface water sources and is not metered. At present, we cannot know for sure the full extent of benefits or impacts from drip irrigation.

share an aquifer with regions D, I, or J—are anticipated to be incrementally worse. The cause-and-effect relationship is not well defined under such conditions, but the best resource to use when attempting to establish a cause-and-effect relationship under such conditions is to demonstrate how historical impacts may be similar to the current condition described here; thus, the most applicable resources are the USGS report on Groundwater Depletion in the United States (1900-2008) (USGS, 2013b), and, regarding water availability concerns that are shared with Mexico we refer to information from the U.S. Congressional Research Service, the USGS, and Texas A&M University (Carter et al., 2015; USGS, 2013a; and, Eckstein, 2011, respectively).[16] Specifically, the report states, "Cumulative total groundwater depletion in the United States accelerated in the late 1940s and continued at an almost steady linear rate through the end of the century. In addition to widely recognized environmental consequences, groundwater depletion also adversely impacts the long-term sustainability of groundwater supplies to help meet the Nation's water needs" (USGS, 2013b). Therefore, one may consider the incremental, long-term impacts with respect to water availability to be significant and adverse in regions B, C, D, I, J, and U, as well as corresponding regions in the northeastern and northcentral reaches of Mexico that share an aquifer with regions D, I, or J. These conditions are anticipated to occur even if a final rule were not enacted. Under such conditions, individuals on Native American reservations in regions B and J may be disproportionately adversely impacted as continued groundwater drawdown could have potential environmental impacts including socioeconomic impacts related to access to water on reservations.

State agencies, the federal Government, and some non-governmental organizations continue to seek new methods to reduce or control these expected significant effects nationwide. Examples of programs that work towards water conservation are State Water Conservation Districts and the National Association of Conservation Districts. These programs work with users throughout their States and districts to develop techniques and technologies that reduce water use, and implement water savings incentive programs.

Sprouting operations – water availability

The majority of the 285 covered sprouting operations draw from municipal water already (FDA, 2013b); only minimal adverse (not significant), local and not significant impacts may occur from water treatment effluent, and no nationwide or regional impacts are anticipated to water availability from those few operations that may connect to municipal water supplies. These small numbers of operations nationwide are not anticipated to significantly contribute to cumulative impacts nationwide or regionally.

Water quality

As discussed in Chapter 4.7, the flexibility in meeting FDA's proposed water quality standard is likely to limit the need to use chemical treatment of a water source with poor water quality. It is also likely that a farmer might add a post-harvest mechanism to allow for added pathogen die-off or removal. Similar to water availability (discussed immediately above), water quality is a current and ongoing problem throughout the U.S. and is exacerbated by all the same influences as is water availability. As discussed under the No Action Alternative (Chapter 4.1), decreasing water flow

[16] This study, including data the study used, is discussed in Chapter 3.1.

and supply tends to increase the concentrations of water contaminants that may otherwise be diluted under higher water flow conditions.

While FDA does not anticipate the environmental impacts of the rule associated with water quality to significantly contribute to water quality concerns (see Chapter 4.7), current conditions are expected to be somewhat worsened. However, sustained, long-term water treatment may not be required because the added flexibility to account for die-off and/or removal is anticipated to result in few, intermittent impacts that are not significant because these steps may be as simple as allowing sufficient time between final application of agricultural water in the field and harvest. Water quality would be expected to return to ambient conditions.

Under these ongoing conditions, regions that are important for water quality issues and covered produce include regions A, B, C, L, R, T, and U (see Chapter 4.1).

It is important to note that many growers of fresh produce already participate in programs that have integrated food safety measures for their agricultural water. Examples of these are found in Table 2.1-1 in Chapter 2.1, and in Table 5.3-1 above. Participation in many of these programs is voluntary; however, the practices of these programs are often mandatory for those who choose to participate. A few programs, such as T-GAPs, are mandatory for growers of certain commodities. Tables 2.1-1 and 5.3-1 do not represent a comprehensive list of programs. There may be similar programs in other states. For programs such as the CA and AZ LGMA, which contain a high number of the growers that may be subject to a final Produce Safety Rule, many aspects of those programs contain more stringent numeric water quality requirements than what FDA proposes. The same is true for programs such as T-GAPs in Florida, which contributes to a high percentage of the tomatoes consumed nationally. Some other state and industry marketing programs may have high standards, but FDA does not know how such programs are audited and enforced. The USDA GAP&GHP program is an example of an audited program for participants, and the program follows the recommendations FDA provided in its 1998 Guide (FDA, 1998, see also Table 5.3-1, Chapter 1.9, and Chapter 2.1).

While FDA does not know how many growers of covered produce may participate in programs described here, it is evident that for representative agreements such as T-GAPS and CA/AZ LGMA, many growers that may be affected by the requirements in the PS PR already participate in these more stringent programs. FDA does not anticipate that a final rule would lead to changes to the requirements of those programs so that they become less stringent.

Ongoing programs that aid in determining the total challenges associated with water quality and work to preserve and improve water quality include federal and state required NPDES programs and permits and nutrient management plans that are required for certain farmers in 45 states; the ongoing efforts to improve municipal separate storm sewer systems (MS4) and minimize TMDLs of certain common contaminants; and continued improvements to municipal water treatment systems.

Biological soil amendments of animal origin – water quality and availability
If a farmer is permitted to use an application interval of 0 days between the application of untreated or treated manure and harvest, there would be no substantial change from the baseline condition that would result in significant impacts to water quality or availability.

Biological and Ecological Resources –
As discussed in Chapter 4.7 under the preferred alternative, adverse effects to biological and ecological resources relevant to groundwater drawdown are not expected. Although the potential cumulative effects from groundwater drawdown relative to existing and expected ongoing conditions may potentially be significant, it is important to also consider the context of human influences along with conservation measures that exist and that are expected to continue.

In addition to water availability, potential cumulative effects on biological and ecological resources would include the pressures of climate change, human development (residential and commercial and its associated environmental effects), and the continued increase in invasive plants and animals that so often disrupt local and regional ecosystems and species populations (see Chapter 3.2.1). Energy development, such as oil and gas exploration activities nationwide, have an additive adverse effect to biological diversity, productivity, and fertility that results from increased levels of toxins contributed to the environment and loss of habitat that provides food and cover for all types of species.

With respect to water quality, potential adverse effects may occur from the use of disinfectants to treat poor quality water in certain areas. Disinfectants may be useful for reducing hazards that may cause foodborne illnesses; however, many of these disinfectants may form harmful byproducts. EPA-registered pesticide products are evaluated to determine potential environmental effects and potential impacts to human health specific to their use. The persistence of chemicals (*e.g.*, antimicrobials or disinfectants) in the environment may adversely influence non-target systems (*e.g.*, wetlands and riparian ecology) and have further indirect effects to flora and fauna coming into contact with those chemicals. If a grower were to choose to use chemical treatment to bring water into compliance, sustained, long-term water treatment may not be required because the added flexibility to account for die-off. Providing that any pesticide that is EPA-registered and is handled and applied in accordance with labeling requirements, which we have determined to be the reasonably foreseeable use of such products, such uses should not result in significant environmental impacts to vegetation, wildlife, and wetland resources. There would be no anticipated impact to the sustainability of vegetation or wildlife at the regional or national level. Impacts to wetlands or waters would not be significant because water quality conditions would be expected to return to ambient conditions. Additionally, as long as the pesticides are handled and applied according to label directions, which we have determined to be a reasonably foreseeable use (see Chapter 4.1 and 4.2, and Appendix E), we do not expect significant environmental impacts to result. Any potentially adverse effects that are associated with the proper use of pesticides may be somewhat limited because a high number of growers in key growing regions, such as California, Arizona, and Florida (Regions C, D, and U), already participate in marketing agreements that have more stringent numeric water quality standards than what FDA has proposed, and are already using water that would be in compliance with the proposed standard. As a result, such impacts would not be the result of the PS PR, if finalized as proposed.

Minimization measures that are available under water resources (discussed in the subheading for water resources within this same chapter) or that are currently being implemented by state agencies and other entities involved in water conservation would contribute to any incremental beneficial effects to biological and ecological resources as well. In addition, (non-water-related) conservation programs exist across the U.S. and are implemented by both public and private agencies. Chapter 4.1 cites additional programs that, through public policy, afford additional conservation protection initiatives, such as the 2014 Farm Bill. The cumulative impacts to biological and ecological resources, unlike water, are more difficult to predict on a wider regional or nationwide basis. The cause-and-effect relationship between human influences and watersheds can be drawn more closely for watersheds that are shared throughout regions. In contrast, biological and ecological resources impacts may be more localized (*e.g.*, whole watersheds may be impacted by contributing factors, but species within the watershed may adapt to changes and potentially thrive, or may be adversely impacted by specific influences in portions of the watershed). Because FDA does not anticipate significant impacts to biological and ecological resources on a regional or national level as a result of the rule, and because there is a prevalence of private and public conservation programs available, the potential cumulative environmental effects may be considered as not significant.

With respect to subpart I (grazing), if animals are presently permitted in the field, the more likely management decision would be to factor in the crop and region in which the crops are grown to allow for consideration of late growing seasons and other factors when determining when to remove the animal from the field at some time during the planting to harvest interval, which provides flexibility for farmers to make the decision on an appropriate time interval, based on the farm's operation. Because dual-purpose operations are mostly anticipated to have confined grazing or other areas for livestock already (livestock management does not occur in produce fields, as livestock, if allowed to graze in produce fields would consume much of the commodity), removing the animal from fields where covered produce may be grown, relative to a planting/harvest interval, is not anticipated to result in adverse impacts beyond baseline conditions.

With respect to subpart I (wildlife intrusion), the most likely management decision would be to evaluate whether produce can be harvested safely and, as appropriate, not harvest a field or part of a field that is reasonably believed to be contaminated from wildlife intrusion. There would be no expected environmental impacts to biological or ecological resources under such a management decision.

Any measures taken to exclude wildlife (including measures to clear land to facilitate monitoring) may involve the use of herbicides, rodenticides, or other materials that may have short-term toxic effects to water resources, biological resources and ecosystems directly adjacent to the farm, and soils. These impacts may be reduced through proper use and handling in accordance with labeling requirements, which we determined to be a reasonably foreseeable use. Therefore, we do not expect significant impacts vegetation or wildlife (see Chapters 4.1 and 4.2, and Appendix E under the comment summary heading "Definition of Significance: Standards Directed to Domesticated and Wild Animals"). Impacts to wetlands or waters would not be significant because water quality conditions would be expected to return to ambient conditions. In addition, given the very low

number of farms that could be affected (between 1.5 and 8 percent of covered farms), there would be no anticipated impact to the sustainability of vegetation or wildlife, or to water quality at the regional or national level. Through the use of wildlife removal in accordance with state and local regulations (such as through hunting and trapping permits) (see Chapter 4.6 on hunting and trapping permit discussions), adverse cumulative effects may be effectively minimized and considered not significant. Additionally, to the extent growers use pest management plans, adverse impacts could be reduced even further.

Note that proposed § 112.84 does not require covered farms to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. The preferred alternative, and more likely management decision that a farmer may make, is to monitor their fields and evaluate whether produce can be harvested safely.

Soils –

Land subsidence

Under this cumulative effects analysis, it is important to compare the potential anticipated cumulative impacts to soils related to groundwater drawdown that may occur from the PS PR, if finalized as proposed (see water resources above). In Chapter 4.7, under the preferred alternative, significant adverse impacts related to groundwater drawdown and the related adverse impacts to soils are anticipated (although the added flexibility in meeting FDA's water quality standard and in light of public comments on the supplemental rule that indicate that because of the added flexibility, a management decision to switch to groundwater sources is not anticipated to be the preferred management decision). In light of the potential significant adverse effects related to groundwater drawdown (these effects are ongoing, absent of any final rule, and would be anticipated even if a rule were not enacted (see USGS, 2013b)), we expect that continued adverse impacts will result related to land subsidence. Regions that may be most impacted by land subsidence (as discussed in Chapter 4.1) include regions B, C, D, I, J and U, as well as corresponding regions in the northeastern and northcentral reaches of Mexico that share an aquifer with regions D, I, or J. Because land subsidence results in irreversible effects to soils, such impacts in regions B, C, D, I, J, and U, as well as corresponding regions in the northeastern and northcentral reaches of Mexico that share an aquifer with regions D, I, or J, may be considered significantly adverse.

Measures that promote water conservation across the nation would potentially reduce the severity of continued land subsidence.

Soil quality

In general, agriculture has lasting (but not irreversible) adverse effects to the natural functions of soils, such that soils require more intense nutrient management, as well as management of biological and physical functioning, to sustain crop yields (Chapter 3.2). The effects to agricultural soils nationwide has been improved through the use of more natural fertilizers (*e.g.*, treated and untreated manure and green manuring) and the employment of no-till management practices and cover crops. However, where the use of natural fertilizers is decreasing (see Chapter 3.4.3.1), the use of cover crops and no-till techniques is increasing. This has a beneficial impact on soils with respect to agricultural practices.

Relative to all U.S. cropland, the NRCS conducts a National Resources Inventory (NRI) every five years as a means to assess the status, condition, and trends in soil, water, and other natural resources on agricultural lands.[17] The most recent survey results show that 1.725 billion tons of soil is lost per year due to water erosion (960 million tons/year) and wind (765 million tons/year). However, when this information is reviewed over a 25-year period (1982 to 2007), the NRCS found that cropland soil erosion has been reduced by an estimated 43 percent (USDA NRCS, 2007). This is attributed to improved soil conservation efforts nationwide.

With respect to soil health and impacts related to subpart F (untreated or treated), if a farmer is permitted to use an application interval of 0 days between the application of untreated or treated manure and harvest, there would be no substantial change from the baseline condition that would result in significant impacts to soil resources. Therefore, FDA expects that the cumulative effects nationwide related to soil health and BSAs of animal origin are not expected to be significant.

With respect to subpart I (grazing and wildlife intrusion taken together), in most cases, covered dual- or multi-purpose operations already have fields that are dedicated pasturelands and would not, under normal conditions, be rotated in for crop land. Any impacts to soils in these areas are most likely already occurring, and therefore, no significant impacts from grazing are expected on soils under any management decision or alternative as a result of the PS PR, if finalized as proposed.

In terms of programs that help to minimize potential adverse environmental impacts, the USDA Conservation Practices program helps farmers better manage their soil resources and reduce the effects of soil loss and erosion. In addition, USDA and states established Conservation Districts that help farmers employ measures that reduce adverse impacts to soils and preserve soil quality, and universities conduct research in conjunction with Federal agencies to help develop new techniques and technologies that farmers may use to further conserve soil resources.

Waste Generation, Disposal, and Resource Use – For untreated BSAs of animal origin, if a farmer is permitted to use an application interval of 0 days between the application of untreated manure and harvest, there would be no substantial change from the baseline condition that would result in significant impacts to waste generation, disposal, or use of the resource. Therefore, no significant environmental impacts would be expected over the existing conditions. With respect to both untreated and treated BSAs of animal origin, the use of chemical fertilizers in place of treated BSAs of animal origin as a nutrient source is unlikely to occur under this alternative because the alternative does not restrict the timing of the use of BSAs, but would impose a requirement to apply in a manner that does not contact covered produce.

Air Quality and Greenhouse Gases – Air quality (and related greenhouse gas and energy usage) impacts from agriculture that are already occurring include, among others, the generation of methane from animal operations (including distribution/transportation of manure, composting, and use on fields), use of fuels to manage farming operations (including equipment, vehicles, and

[17] These surveys are not specific to crops or farms that may be covered by the proposed rule. Therefore, these data were not effective for assessing impacts associated with the PS PR.

facilities), and use of chemical fertilizers. Criteria pollutants and other greenhouse gases are generated daily by commercial and residential development, oil and gas exploration, and other human activities. The net generation of criteria pollutants and other greenhouse gases are not expected to change considerably at a regional or national level as a result of finalizing the PS PR because the preferred alternative and related most likely management decisions are not expected to contribute to air emissions of criteria pollutants or GHG emissions that may result in considerable public health concerns at a regional or national level.

No new methane production is expected because the amount of animal waste that is generated is not expected to change as a result of the PS PR.

Socioeconomics and Environmental Justice –With respect to cumulative impacts, farms all over the U.S. are subject to pressures from water availability and water quality as a result of competing commercial, residential, and industrial water interests, and the interests of public and private oil and gas exploration efforts. Farms, like the rest of U.S. businesses and residents, are subject to increasing costs for goods (equipment) and services (power and water for example). The result has been an overall increase in operating costs, and an overall decrease in farming (see trends as discussed in Chapter 1.9). Farms have been very adaptable, finding new and innovative methods to plant and harvest crops, regulate the use of water, and apply nutrients to soils (through the use of nutrient management plans – which when accompanied with regular soil testing as most plans accomplish, allow the farmer to better manage nutrient application in a more efficient manner to different parts of even the same field).

FDA considered the economic costs of the PS PR to covered farms when considering the environmental alternatives and associated socioeconomic impacts. The average projected per-farm cost of complying with the provisions of the PS PR, if finalized as proposed, is approximately $4,477 for very small farms, $12,384 for small farms, and $29,545 for all other covered farms. While small and very small farms may not be able to afford this added cost burden, FDA anticipates that farms that are not able to qualify for an exemption to reduce the cost of compliance would be the most likely to make management decisions which would either result in them not being subject to the provisions of the PS PR or that would make them exempt from the provisions. As discussed in Chapters 4.7 and 4.2, based on the comments that FDA received on the supplemental proposed rule, FDA does not expect that primary farm operators would cease growing covered produce as a preferred management decision except in select instances which are often driven by outside pressures unrelated to this rule (an example cited in Chapter 4.7 includes the state of California that pays farmers to keep land fallow in order to divert water to the cities).

As discussed in Chapter 4.7, if non-covered produce or other agricultural crops that are not produce are grown, requirements to maintain certain water quality conditions would be dependent on any existing state regulations or industry marketing agreements. The type of crop a farmer may select to grow would also be dependent upon the region's climate, soils, water availability, and may

involve a decision whether the existing farm's equipment and infrastructure would be sufficient, or would need to be updated, modified, or bought to accommodate a new type of crop.[18]

With respect to subpart F, since there is no substantial change from the existing conditions, there are no additional costs associated with this provision that may result in related impacts to farm employment or loss of income.

Environmental Justice – The overall cost of compliance for farms could potentially result in higher produce prices for consumers, including minority consumers. However, we expect that demand for produce commodities would eventually be met by other growers in the region, growers in other regions, or international suppliers. As a result, we expect commodity prices to stabilize. Therefore, we do not expect significant impacts to disadvantaged populations as a result of the rule's impact to consumer costs.

As discussed in Chapter 1.9, FDA considers in this Final EIS potential impacts to minority principal farm operators and farmworkers (see also Chapter 3.7.3). USDA NASS survey data provides information on principal operators of farms. Available information related to farmworkers is less extensive, and FDA relied on limited statistics provided by USDA ERS and the U.S. Department of Labor. There are no data specifically reported for farmworkers on produce farms. The available data sources are also limited in terms of farmworker ethnicity and income. Based on this limited data available, and consistent with the scope of the EIS, regions where there are populations of minority farmworkers that may be impacted by the rule, if finalized as proposed, include regions C, D, I, and J. The only state for which state-specific income data are reported is California, which is region C. Potential impacts to farmworker employment may be dependent upon multiple factors including (but not limited to) average annual farm income, estimates for crop yield, and commodity prices. Increases in farm operating costs may also impact farm worker employment. Farmworker employment can also be seasonal (USDA ERS, 2014a).

Minority groups: When considering the "meaningfully greater" threshold of 11.6 percent (see Chapters 3.7 and 4.1), regions that are important for identifying potential impacts to minority primary operators are regions A, B, C, D, W, and V.

Principal operators

FDA is not aware of any federal or state programs that have been implemented or that are presently being considered that may adversely or disproportionately affect minority operators, except that the same economic pressures that are discussed in this chapter and in Chapter 1.9 apply to all farmers. Minority primary operators manage farms of all size classes potentially affected by the provisions of the PS PR and would need to make the same management decisions as primary operators generally regarding whether to comply with the rule or to cease growing covered produce based on cost considerations. As discussed in Chapter 4.7, because of the greater added costs proportional to the amount of sales, primary operators for very small farms are generally more

[18] FDA received public comment on the likelihood that farmers may make certain management decisions that may result in environmental impacts related to other crops farmers may grow in order to avoid complying with the rule, or that may result in farms going out of business. Our response to these comments are found in Appendix E under the comment heading "*Assessment of Management Decision to Cease Production*."

likely than primary operators of larger farms to make management decisions to stop growing crops altogether if the farm manages livestock operations that also grow small amounts of covered produce, although many such diversified farming-livestock operations would likely be excluded based on the new proposed monetary threshold for excluded farms applied to sales of produce only rather than sales of food, or may be eligible for qualified exemptions (in the very small and small farm categories). Because of the potential exclusion based on sales or eligibility for qualified exemptions that may be available to very small and small farms, and because there are management decisions available to all covered farms that may reduce the impacts related to employment or income (*e.g.*, use a part-harvest rinse as compared to treating irrigation water, switch to a non-covered crop), we do not expect there to be disproportionate cumulative impacts to minority primary operators covered by the rule. As noted above, potentially adverse impacts to minority primary operators are more likely to occur in regions A, B, C, D, W and V.

Minority farmworkers

As discussed in Chapters 3.7 and 4.7, and above, regions where there are populations of minority farmworkers that may be impacted by the rule, if finalized as proposed, include regions C, D, I, and J. Costs incurred by farms of all sizes may result in the farm either increasing the costs of its produce for consumers, or may involve the farm primary operator terminating the employment of full-time, part-time, or seasonal worker(s) in order to defray their operating costs. Regions where such actions may adversely disproportionately affect minority farm workers include regions C, D, I, and J.

Native American operators: As discussed in Chapter 4.7, based on available data, it appears that no more than 5 percent of farms with a Native American principal operator would be covered by the rule. Despite this relatively low number of total Native American owners/operators who may be covered by the rule, there is a potential that added operating costs associated with the rule could impact a disproportionate number of Native American farmers compared to farmers as a whole, given that the average sales for a farm with a Native American principal operator is 30 percent lower than a farm with a non-Native American principal operator farm (per the 2007 Agricultural census). The average reported agricultural product sales for Native American operated farms is $40,331, compared to an average of $134,807 for all farms. The average potential per-farm cost of approximately $4,500 could be disproportionally burdensome for Native American operated farms as it would comprise approximately 11 percent of their average annual sales, compared to 3 percent of the average annual sales of all farms.[19] However, the potential impacts for very small and small farms may be entirely mitigated to the extent these farms are eligible for a qualified exemption; therefore, potential incremental cumulative impacts may also be mitigated and would not be considered significant, such that Native American principal operators would not be disproportionately affected by the rule.

Water availability-related impacts

As discussed in Chapter 4.7 and the discussion above related to water availability, individuals on Native American reservations in regions B and J may be disproportionately adversely impacted as a result of continued groundwater drawdown. These conditions are a result of current and projected

[19] $4,500 divided by $40,331 equates to approximately 11 percent.

ongoing impacts related to water use throughout the U.S. and are anticipated to occur even if a final rule were not enacted.

Low-income: As discussed in Chapters 3.7.3 and 4.7, this class includes any persons whose median household income is at or below the 2012 HHS poverty guidelines (see 77 Fed. Reg. 4034, January 26, 2012). The HHS poverty guideline figure for a family of four in 2012 was set at $23,050. According to the USDA Agricultural Resource Management Survey data sheet, *Principal farm operator household finances, by ERS farm typology,* in 2012, median principal farm operator household income (an average of the farm and off-farm household incomes of residence farms, intermediate farms, and commercial farms) was $68,298.[20] This exceeds the $23,050 guideline as well as all other 2012 HHS poverty guidelines for families of up to eight members (see Table 3.7-17). While FDA acknowledges that there still may be low-income principal operators that may be adversely impacted by the costs associated with the rule, based on the aforementioned available information, we cannot reasonably identify low-income populations on a national or regional level that could be affected by the PS PR.

Low-income farmworkers: As discussed in Chapter 4.7, impacts may involve the farm principal operator terminating the employment of full-time, part-time, or seasonal worker(s) in order to defray their operating costs. Consistent with the scope of the EIS (see Chapter 1.9), based on data provided by the U.S. Department of Labor (information reported for California) (DOL, 2000 and 2005), region C has populations of low-income farmworkers that may be disproportionately impacted by the rule. Note that other regions may experience similar impacts, but there is not enough data available to understand which regions may specifically be impacted.

Human Health and Safety –

Foodborne illnesses prevented

Similar to the analysis in Chapter 4.7, FDA estimates that the number of foodborne illnesses prevented when considering the rule as proposed, all provisions, is 1.57 million annually (FDA, 2014b). This represents a significant beneficial outcome to human health.

Human health impacts

Any management decision that may adversely affect primary operator and farm worker health would potentially be related to chemical treatment of agricultural water. FIFRA mandates that EPA regulate the use and sale of pesticides to protect human health and preserve the environment, and the risks to worker health are minimized when using proper handling techniques including using recommended personal protective equipment in accordance with labeling requirements or product recommendations (*e.g.*, chemically resistant gloves to avoid exposures that may otherwise cause unreasonable health effects) as described by the manufacturer. We have determined that the proper use of pesticides is a reasonably foreseeable use (see Chapter 4.1, 4.2, and Appendix E under the headings "Compliance with Another Agency's Requirements, " and "Impact on Minority Groups Other than Native Americans"), and therefore that no significant impacts will result from the chemical treatment of agricultural water.

[20] There is limited data for principal farm operator income other than on a national level.

Comparison of potential cumulative impacts

As discussed at the beginning of this chapter, the comparison is accomplished for alternatives under Subpart A, because if a farm is covered under subpart A, then the other provisions of the rule apply. The potential environmental impacts for the rule are provided in Chapters 4.2 through 4.7, and a summary of these impacts by alternative under subpart A is provided in Chapter 4.7.

Table 5.5-1 provides a summary of the potential cumulative environmental and related socioeconomic and public health impacts from finalizing the PS PR and considering other past, present, and reasonably foreseeable future federal and non-federal actions.

Table 5.5-1. Comparison of potential cumulative impacts by alternative for subpart A

		≤ $25,000 * total produce excluded Alternative I	≤ $50,000** Food excluded Alternative II	≤ $100,000** Food excluded Alternative III	≤ $25,000 covered produce excluded Alternative IV
Comply with the rule	Covered Farms	35,503	28,253	20,140	Slightly fewer than Alternative I
	Excluded Farms	130,204	Greater than Alternative I	Greater than Alternative II	Slightly greater than Alternative I
	Environmental impacts (Chapters 4.1 – 4.7)	Greater than baseline	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Economic impacts (domestic costs annually)	$540.49 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Domestic benefits (health-related cost savings)	$930 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Public health benefits (foodborne illnesses prevented annually)	1.57 million	Less than Alternative I (less foodborne illnesses prevented)	Less than Alternative II (less foodborne illnesses prevented)	Slightly fewer than Alternative I (less foodborne illness prevented)
Switch to non-covered crop	Covered Farms	Less than 35,503	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Excluded Farms	Greater than 130,204	Greater than Alternative I	Greater than Alternative II	Slightly greater than Alternative I
	Environmental impacts (Chapters 4.1 – 4.7)	Less impacts compared with complying	Less impacts compared with Alternative I	Less impacts compared with Alternative II	Slightly fewer than Alternative I
	Economic impacts (domestic costs annually)	Less than $540.49 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Domestic benefits (health-related cost savings)	Less than $930 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Public health benefits (foodborne illnesses prevented annually)	Less than 1.57 million	Less than Alternative I (less foodborne illnesses prevented)	Less than Alternative II (less foodborne illnesses prevented)	Slightly fewer than Alternative I (less foodborne illness prevented)

*As updated in the supplemental PRIA (FDA, 2014b).
**The associated estimates are found within the 2013 PRIA (FDA, 2013b).

Water Resources- As discussed in Chapter 4.7 and within the cumulative impact discussion presented at the beginning of Chapter 5.5 under the subheading for water resources, based on our qualitative analysis, we do not consider impacts to water resources to be significant because the flexibility in meeting the proposed water quality standard is likely to limit the need to use chemical treatment of a water source with poor water quality. It is also likely that a farmer might add a post-harvest mechanism to allow for added microbial die-off or removal. The potential exception is related to groundwater withdrawal, where significant adverse long-term impacts to water availability and soils (related to the irreversible impacts from land subsidence) may continue to occur in regions B, C, D, I, J, and U, as well as corresponding regions in the northeastern and northcentral reaches of Mexico that share an aquifer with regions D, I, or J, as a result of excessive groundwater use. These effects are the result of the current condition and projected ongoing impacts related to water use throughout the U.S., and any further contribution to these impacts would be significant. Individuals on Native American reservations in regions B and J may be disproportionately adversely impacted as a result of continued groundwater drawdown and reduced access to water on reservations.

The issue of downstream degradation of water quality by salts, agrochemicals, and toxic leachates is a serious environmental problem. Regions that grow covered produce and that are already experiencing high exceedances in state surface water quality levels based on CWA Section 303(d) requirements (33 U.S.C § 1313(d)) (compare Figure 3.1-15 in Chapter 3.1.3.9 to Figure 1.7-4 in Chapter 1.7) and groundwater quality impairments (primarily from coliform bacteria) include regions A, B, C, L, R, T, and U (compare Figures 3.1-16 and 3.1-17 in Chapter 3.1.3.9 to Figure 1.7-4).[21]

Biological and Ecological Resources- FDA does not anticipate significant impacts to biological and ecological resources as a result of the rule because there would be no anticipated impact to the sustainability of vegetation or wildlife at the regional or national level. Any impacts to wetlands or waters would not be significant because water quality conditions would be expected to return to ambient conditions. In addition, the prevalence, use and effectiveness of measures that promote private and public conservation may further minimize any potential cumulative environmental effects.

Soils- Relative to soil quality and subpart F, there would be no substantial change from the baseline condition that would result in additional impacts to soil resources. Potential impacts related to land subsidence is addressed under Water Resources, above.

Waste Generation, Disposal, and Resource Use- Waste generation, disposal and resource use would remain substantially unaffected from baseline conditions, and therefore, we do not expect additional significant environmental impacts.

Air Quality and Greenhouse Gases- With respect to air quality and GHGs, any contributions of air emissions of criterial pollutants or GHG emissions are not expected to result in considerable

[21] Regions A, B, C, L, R, T, and U represent the majority of the east and west coast states.

public health concerns at a regional or national level; therefore, we do not expect significant impacts.

Socioeconomics and Environmental Justice- Based on the PRIA and supplemental PRIA (FDA 2013b and 2014b, respectively), and based on our qualitative analysis, small and very small farms may be more adversely affected by such costs; however, these farms may be eligible for qualified exemptions, which would effectively mitigate costs of the rule. As small and very small farms may not be able to afford this added cost burden, farms that are not able to qualify for an exemption to reduce the cost of compliance would be the most likely to make management decisions which would either result in them not being subject to the provisions of the PS PR or that would make them exempt from the provisions. As discussed in Chapters 4.7 and 4.2, based on the comments that FDA received on the supplemental proposed rule, FDA does not expect that primary farm operators would cease growing covered produce as a preferred management decision except in select instances which are often driven by outside pressures unrelated to this rule (an example cited in Chapter 4.7 includes the state of California that pays farmers to keep land fallow in order to divert water to the cities).

If non-covered produce or other agricultural crops that are not produce are grown, requirements to maintain certain water quality conditions would be dependent on any existing state regulations or industry marketing agreements.

With respect to subpart F, since there is no substantial change from the existing conditions, we do not expect any significant impacts to result.

Minority primary operators

Principal operators for very small farms are generally more likely than primary operators of larger farms to make management decisions to stop growing crops altogether if the farm manages livestock operations that also grow small amounts of covered produce, although many such diversified farming-livestock operations would likely be excluded based on the monetary threshold for excluded farms applied to sales of produce only rather than sales of food. Because of the potential exclusion based on sales or eligibility for qualified exemptions that may be available to very small and small farms, and because there are management decisions available to all covered farms that may reduce the impacts related to employment or income, we do not expect there to be disproportionate cumulative impacts to minority primary operators. Any potentially adverse impacts to minority primary operators that do result are more likely to occur in regions A, B, C, D, W and V.

Minority farmworkers

As discussed in Chapters 3.7 and 4.7, and above, costs incurred by farms of all sizes may result in the farm either increasing the costs of their produce for consumers, or may involve the farm primary operator terminating the employment of full-time, part-time, or seasonal worker(s) in order to defray their operating costs. Regions where such actions may adversely disproportionately affect minority farm workers include regions C, D, I, and J.

Native American operators

As discussed in Chapter 4.7, based on available data, it appears that no more than 5 percent of farms with a Native American principal operator would be covered by the rule. Despite this relatively low number of total Native American owners/operators who may be covered by the rule, there is a potential that added operating costs associated with the rule would impact a disproportionate number of Native American farmers compared to farmers as a whole, given that the average sales for a farm with a Native American principal operator is 30 percent lower than a farm with a non-Native American principal operator farm (per the 2007 Agricultural census). The average reported agricultural product sales for Native American operated farms is $40,331, compared to an average of $134,807 for all farms. The average potential per-farm cost of approximately $4,500 could be disproportionally burdensome for Native American operated farms as it would comprise approximately 11 percent of their average annual sales, compared to 3 percent of the average annual sales of all farms.[22] However, the potential impacts for very small and small farms may be entirely mitigated to the extent these farms are eligible for a qualified exemption; therefore, potential incremental cumulative impacts may also be mitigated and would not be considered significant such that Native American principal operators would not be disproportionately affected by the rule.

As discussed in Chapter 4.7 and the discussion above related to water availability, individuals on Native American reservations in regions B and J may be disproportionately adversely impacted as a result of continued groundwater drawdown. These conditions are a result of current and projected ongoing impacts related to water use throughout the U.S., and are anticipated to occur even if a final rule were not enacted.

Low-income farmworkers

Regions where such actions may adversely disproportionately affect low-income farmworkers include region C.

For any alternative where fewer farms would be covered by the rule (Alternatives II, III, and IV, see Table 5.5-1) the potential cumulative environmental, socioeconomic, and public health impacts would be less than what may occur under Alternative I.

- The expected annual economic impacts nationwide would decrease but the expected per-farm costs are anticipated to remain the same as Alternative I.
- The expected environmental impacts, both adverse and beneficial, would decrease nationwide, but not to the extent that would reduce any already significant impacts to a less than significant level.
- The expected number of foodborne illnesses prevented would decrease, which means fewer public health benefits would be experienced.

[22] $4,500 divided by $40,331 equates to approximately 11 percent.

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6.0 Potential Irreversible and Irretrievable Commitment of Resources

40 CFR 1502.16 requires a review of any irreversible and irretrievable commitments of resources that would be involved should the PS PR be implemented. An irreversible and irretrievable commitment of resources is related to the use of non-renewable resources and the effect that the use (or depletion) of these resources would have on future generations. Irreversible effects primarily result from the use or destruction of a specific resource that cannot be replaced within a reasonable time frame, such as fossil fuels. Irretrievable resource commitments involve the loss in value of an affected resource that cannot be restored as a result of the action (e.g., groundwater depletion).

Relating to the proposed action and potential alternatives, irreversible adverse impacts could result to groundwater and soil structure as a result of groundwater depletion and related land subsidence (gradual settling or sudden sinking of Earth's surface), which is likely to continue to occur and could be exacerbated if farm operators choose to withdraw groundwater in excess of current conditions for the purpose of complying with provisions of the PS PR, if finalized. Land subsidence as a result of groundwater withdrawals has occurred in areas of the country where large volumes of groundwater have been- and continue to be removed from the aquifers. Chapters 3.1.3.11 and 3.3.3.5 present details on the extent and history of groundwater and land subsidence associated with groundwater withdrawal, respectively. Potential groundwater depletion and subsidence impacts to soils are discussed in Chapter 4 as part of the No Action alternative (Section 4.1), and in discussion of subpart A (Chapter 4.7.1) and subpart E (Chapter 4.2). Compliance with the proposed standard directed to agricultural water, if finalized, could cause farm operators to replace surface water sources with groundwater, thereby causing increased groundwater pumping, aquifer depletion, soil subsidence, and soil structure destruction. As a result of these potential impacts, it is FDA's analysis that groundwater depletion and land subsidence may be the only irretrievable resource commitments associated with compliance with the PS PR. However, as discussed in Chapter 4.2, FDA has heard from stakeholders that, given the flexibility added to the proposed requirements for agricultural water sources, it is less likely that operations will need to switch water sources to meet the proposed agricultural water standards, if finalized, thereby alleviating much of the potential for exacerbating existing groundwater depletion and land subsidence issues.

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7.0 Potential Unavoidable Adverse Environmental Impacts

Under 40 CFR 1500.2(e), Federal agencies shall, to the fullest extent possible, use the NEPA process to identify and assess reasonable alternatives to proposed actions that will avoid or minimize adverse effects of these actions upon the quality of the human environment. This chapter discusses significant unavoidable impacts for which either no mitigation or only partial mitigation is feasible. An evaluation of impacts associated with the No Action alternative and the potentially significant provisions of the PS PR is included in Chapter 4. The analysis in Chapter 4 includes a discussion of environmental consequences of the alternatives to the potentially significant provisions, and possible management decisions by farm operators, associated with compliance with the provisions of the PS PR, if finalized.

Potential unavoidable adverse impacts associated with the implementation of the PS PR could occur under the following provision and alternative:

Subpart E – Standards Directed to Agricultural Water

Alternative I: As Proposed. GM ≤ 126 CFU generic *E. coli*/100ml and STV ≤ 410 CFU/100ml with added flexibility for microbial die-off and/or removal

- The flexibility in meeting the proposed water quality standard is likely to reduce the need to use chemical treatment of a water source with poor water quality. It is also likely that a farmer might add a post-harvest mechanism to allow for added microbial die-off and/or removal. As discussed under the No Action Alternative, while there may be current and on-going significant adverse, long-term impacts from lowering the water table, deteriorating water quality, and land subsidence, each resulting from further groundwater withdrawals, such switches to groundwater are already occurring and causing significant adverse impacts that would be independent of the proposed water standard. Any action that may lead to increases in groundwater drawdown would be considered a significant environmental impact. Regions that may be most impacted in terms of potential land subsidence, including any additive effects by switching to groundwater sources, include the regions that already experience the highest groundwater withdrawals; these are regions B, C, D, I, J, and U. Such effects related to groundwater drawdown may further be experienced in the northeastern and northcentral reaches of Mexico, corresponding to groundwater withdrawals from aquifers in regions D, I, and J in the United States. Due to the added flexibility to account for pathogen microbial die-off in the field under Alternative I, coupled with the knowledge that a high amount of potentially affected growers participate in marketing agreements with more stringent numeric water quality standards than what FDA proposes, any potential effects related to Alternative I are not expected to substantially contribute to the current significant adverse conditions to the extent that would occur under Alternatives IV-a, II, IV-b, III, or IV-c.

Alternative II: Generic *E.coli* maximum of 235 CFU/100 ml for any single sample or a rolling GM of no more than 126 CFU per 100 ml

- Under this alternative, switching water source is expected to be the preferred management decision. As compared to Alternatives I or IV-b, this alternative would not have the added

flexibility for pathogen die-off and/or removal; therefore, farmers are more likely to decide to switch water sources, particularly away from surface waters to a cleaner source. If the cleanest available source is groundwater, then existing significant adverse conditions (i.e., water drawdown, potential subsidence, and the related continued degradation of water quality) may continue to be exacerbated but to a greater degree than Alternative I, because the water quality requirements would be more stringent under this alternative and more farms are potentially likely to switch to the groundwater source in numbers that may considerably influence groundwater sources. These impacts are expected to be limited to localized regions and are not expected to be widespread. The regions that may be most affected are B, C, D, I, J, and U, as well as corresponding areas in northeastern and northcentral reaches of Mexico that share an aquifer with regions D, I, and J in the United States. These regions may also experience irreversible effects to soils. Therefore, these impacts under Alternative II related to lowering the water table, deteriorating water quality, and land subsidence, are considered significant adverse.

- Native American Tribes may be disproportionately impacted as groundwater drawdown could have potential environmental impacts including socioeconomic impacts related to access to water on reservations, particularly in regions B and J. Such impacts would be considered significant adverse.

Alternative III: As proposed (i.e., Alternative I), with an additional criterion establishing a maximum generic *E. coli* threshold

- This alternative would be substantially similar to Alternative I; however, the implementation of a maximum threshold for generic E. coli may mean that there may be circumstances when a farmer is not able to account for microbial die-off and/or removal. Such circumstances, however, would be dependent on the numerical criterion of the threshold. Therefore, the likelihood that a farmer may decide to switch to a groundwater source is slightly higher than Alternatives I or IV-a. It is, however, more likely that the farmer would first select to add a post-harvest step to account for additional die-off.

Alternatives IV-a, IV-b, and IV-c: Above three alternatives (considered separately), including drip-irrigated root crops

- Similar to Alternative I, due to the added flexibility associated with this alternative, long-term chemical treatment of agricultural water would not be necessary. Therefore, under Alternative IV-a, switching a water source is not expected to be a preferred management decision. The impacts under Alternative IV-a would be substantially similar to those identified under Alternative I, and slightly fewer impacts as compared to Alternatives III and IV-c. Environmental impacts are expected to be significantly less than those identified under Alternatives II and IV-b.
- Under Alternative IV-b, there may be a greater potential to switch to a cleaner water source or to treat the water source in order to meet the microbial water quality standard as compared to Alternatives I, IV-a, III, or IV-c. The impact analysis under Alternative IV-b would be substantially similar to those identified under Alternative II; therefore, impacts are expected to be greater under this alternative as compared to Alternatives I, IV-a, III, or IV-c.

- Under Alternative IV-c, there is a somewhat greater potential to switch to a cleaner water source or to treat the water source in order to meet the microbial water quality standard as compared to Alternatives I and IV-a, but less of a potential to select these management decisions as compared to Alternatives II and IV-b. The impact analysis under Alternative IV-c would be substantially similar to those identified under Alternative III, therefore, impacts are expected to be greater under this alternative as compared to Alternatives I and IV-a.

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9.0 Acronyms and Abbreviations

A

ACHP - Advisory Council on Historic Preservation
AEU - Animal Equivalent Unit
AFO - Animal Feeding Operation
AMI - American Mushroom Institute
AMS - Agricultural Marketing Service
AOI - Area of Interest
APHIS - Animal and Plant Health Inspection Service
AZ LGMA - Arizona Leafy Greens Marketing Agreement

B

BCAP - Biomass Crop Assistance Program
BEA - Bureau of Economic Analysis
BIA - Bureau of Indian Affairs
BMP - Best Management Practices
BSA - Biological Soil Amendment
BTU - British Thermal Unit

C

Ca - Calcium
CAA - Clean Air Act
CAFF - Community Alliance with Family Farmers
CAFO - Concentrated Animal Feeding Operations
CA LGMA - California Leafy Greens Marketing Agreement
CCAB - California Cantaloupe Advisory Board
CDC - Centers for Disease Control and Prevention
CDHS - California Department of Health Services
CD-ROM - Compact Disk Read Only Memory
CEQ - Council on Environmental Quality
CFR - Code of Federal Regulations
CFU - Colony Forming Unit
CFWC - California Farm Water Coalition
CGMP - Current Good Manufacturing Practices
CH_4 - Methane
Cl_2 - Chlorine
C:N - Carbon to Nitrogen Ratio
COA - Certificate of Analysis
CO - Carbon Monoxide
CO_2 - Carbon Dioxide
CPS - Conservation Practice Standards
CSA - Community Supported Agriculture
CWA - Clean Water Act

CWS - Community Water Systems
CWT - a hundredweight, unit of measurement equal to 100 pounds

D

DACS - Florida Department of Agriculture and Consumer Services
DL - Detection Limit
DNA - Deoxyribonucleic acid
DOE - U.S. Department of Energy
DOL - U.S. Department of Labor
DSHS - Texas Department of State Health Services

E

EA - Environmental Assessment
E. coli - *Escherichia coli*
e.g. - (*exempli gratia*) for example
EHEC - Enterohemorrhagic *E. coli*
EIB - Economic Information Bulletin
EIS - Environmental Impact Statement
EJ - Environmental Justice
EO - Executive Order
EPA - U.S. Environmental Protection Agency
EQIP - Environmental Quality Incentives Program
ERS - Economic Research Service
ESA - Endangered Species Act
EST - Eastern Standard Time
et al. - (*et alia*) and others
et seq. - (*et sequentes* or *et sequential*) and the following

F

FC - Fecal Coliform
FAO - Food and Agriculture Organization of the United Nations
FDA - U.S. Food and Drug Administration
Fed. Reg. - Federal Register
FETRA - Fair and Equitable Tobacco Reform Act
FFDCA - Federal Food, Drug, and Cosmetic Act
FIFRA - Federal Insecticide, Fungicide, and Rodenticide Act
FoodNet - Foodborne Diseases Active Surveillance Network
FR - Federal Register
FRIA - Final Regulatory Impact Analysis
FRIS - Farm and Ranch Irrigation Survey
FSMA - Food Safety Modernization Act
FSVP - Foreign Supplier Verification Programs

G

GAFL - Georgia Florida
GAP - Good Agricultural Practices
GAP&GHP Program - Good Agricultural Practices and Good Handling Practices Program
gdw - Gram Dry Weight
GHG - Greenhouse Gases
GHP - Good Handling Practices
GLP - Good Laboratory Practice
GM - Geometric Mean
GMO - Genetically Modified Organism
GT - Gigaton (or one billion tons)
GWP - Global Warming Potential

H

HACCP - Hazard Analysis and Critical Control Points
HARPC - Hazard Analysis and Risk-based Preventive Controls
HCl - Hydrochloric acid
HClO - Hypochlorous Acid
HHS - U.S. Department of Health and Human Services
HUD - U.S. Department of Housing and Urban Development
HUS - Hemolytic Uremic Syndrome

I

i.e. - (*id est*) in other words; that is to say
IFT - Institute of Food Technologists
IHS - Indian Health Service
IPCC - Intergovernmental Panel on Climate Change
IPM - Integrated Pest Management

J

K

K - Potassium
km^2 - Square Kilometer
km^3 - 1,000 Cubic Kilometer
kGy - Kilogray (absorption of one joule of radiation energy by one kilogram of matter)

L

Lbs - Pounds
LGMA - Leafy Greens Marketing Agreement
L. monocytogene - *Listeria monocytogene*

LP - Liquefied Petroleum
LRR - Land Resource Regions

M

MAF - Million Acre Feet
MAS - Major Aquifer Study
MBTA - Migratory Bird Treaty Act
MCL - Maximum Concentration Limit
MDP - Microbiological Data Program
Mg - Magnesium
MGD - Millions of Gallons Per Day
MGAP - Mushroom Good Agricultural Practices
mg/L - Milligrams Per liter
ml - Milliliter
mV - Millivolt
MMP - Manure Management Planner
MPN - Most Probable Number

N

N - Nitrogen
N_2O - Nitrous Oxide
NA - Not Available
NAAQS - National Ambient Air Quality Standards
NACMCF - National Advisory Committee on Microbiological Criteria for Foods
NaOCl - Sodium Hypochlorite
NASDA - National Association of State Departments of Agriculture
NASPHV - National Association of State Public Health Veterinarians
NASS - National Agricultural Statistics Service
NATTWG - North American Tomato Trade Work Group
NAWQA - National Water-Quality Assessment
NAWS - National Agricultural Workers Survey
NCAI - National Congress of American Indians
NEPA - National Environmental Policy Act of 1969
NH_3 - Ammonia
NH_4^+ - Ammonium Ion
NHPA - National Historic Preservation Act of 1966 as Amended
NIFA - National Institute of Food and Agriculture
NMFS - National Marine Fisheries Service
NMP - Nutrient Management Plan
NO_2 - Nitrogen Dioxide
NOA - Notice of Availability
NOAA - National Oceanic and Atmospheric Administration
NOI - Notice of Intent
NOP - National Organic Program

NOSB - National Organic Standards Board
NOx - Nitrogen Oxides
NPDES - National Pollutant Discharge Elimination System
NPK - Nitrogen, Phosphorous, and Potassium
NPS - U.S. National Park Service
NRCS - Natural Resources Conservation Service
NRI - National Resources Inventory

O

O_3 - Ozone
OCC - Office of the Chief Counsel
OEA - Office of External Affairs
OFVM - Office of Foods and Veterinary Medicine
ORA - Office of Regulatory Affairs
ORP - Oxidation Reduction Potential
OSHA - Occupational Safety and Health Administration
OSU - Ohio State University

P

P - Phosphorous
PAM - Anionic Polyacrylamide
Pb - Lead
PC HF PR - Preventive Controls for Human Food Proposed Rule (also seen in the Final EIS as PC HF and PC HF FR, signifying that this rule has been finalized)
PCR - Polymerase Chain Reaction
PFGE - Pulsed-Field Gel Electrophoresis
PM - Particulate Matter
$PM_{2.5}$ - Particulate Matter (Fine Particles) - diameter less than 2.5 micrometer
PM_{10} - Particulate Matter (Inhalable Course Particles) - diameter from 2.5 to 10 micrometers
PMP - Pest Management Plan
PPM - Parts Per Million
PRIA - Preliminary Regulatory Impact Analysis
PSA - Produce Safety Alliance
PSD - Prevention of Significant Deterioration
PS PR - Produce Safety Proposed Rule
Pub. L. - Public Law

Q

Q&A - Question and Answer
QAR - Qualitative Assessment of Risk

R

RCD - Resource Conservation District of Monterey County
ROD - Record of Decision
ROI - Region of Influence
RWQC - Recreational Water Quality Criteria

S

§ - Section
§§ - Sections
S - Sulfur
SBA - Small Business Administration
SDWA - Safe Drinking Water Act
SIP - State Implementation Plan
SO_2 - Sulfur Dioxide
SOC - Soil Organic Carbon
SOM - Soil Organic Matter
spp. - species
SSA - Sprout Safety Alliance
SSSA - Soil Science Society of America
STEC - Shiga Toxin-Producing *E. coli*
ST PR - Sanitary Transportation of Human and Animal Food Proposed Rule
STV - Statistical Threshold Value
SUME - Survival of Microorganisms in Environment
SWQA - Source-Water Quality Assessment

T

T&E - Threatened and Endangered
T-BMP - Tomato Best Practices Manual
T-GAP - Tomato Good Agricultural Practices
Tg CO_2 Eq. - Teragrams of Carbon Dioxide Equivalent
THM - Trihalomethanes
TMDL - Total Maximum Daily Load
TRI - Toxic Release Inventory
TTHM - Total Trihalomethanes
TTPP - Tobacco Transition Payment Program
TVP - Total Value of Production

U

United Fresh - United Fresh Produce Association
UNEP - United Nations Environment Programme
UNSCEAR - United Nations Scientific Committee on the Effects of Atomic Radiation
U.S. - United States
U.S.C. - U.S. Code

USCB - U.S. Census Bureau
USDA - U.S. Department of Agriculture
USDA AMS - USDA Agricultural Marketing Service
USDA ARS - USDA Agricultural Research Service
USDA CCPO - USDA Climate Change Program Office
USDA ERS - USDA Economic Research Service
USDA NASS - USDA National Agricultural Statistics Service
USDA NRCS - USDA Natural Resources Conservation Service
USFWS - U.S. Fish and Wildlife Service
USGS - U.S. Geological Survey
UV - Ultra-violet
UW - University of Wisconsin

V

VOC - Volatile Organic Compound
VTA - Vegetated Treatment Area

W

WCFS - Western Center for Food Safety
WFA - Wild Farm Alliance
WHIP - Wildlife Habitat Incentive Program
WHO - World Health Organization
WPS - Worker Protection Standard

X

Y

Z

ZVI - Zero Valent Ion

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10.0 Glossary

A

Affiliate - Any facility that controls, is controlled by, or is under common control with another facility.

Agricultural Tea - A water extract of biological materials (such as humus, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. Agricultural teas are held for longer than one hour before application.

Agricultural Tea Additive - A nutrient source (such as molasses, yeast extract, or algal powder) added to agricultural tea to increase microbial biomass.

Agricultural Water - Water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food-contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).

Animal Equivalent Unit - An measurement equal to 1000 pounds of live weight of livestock or poultry farm animals, on an annualized basis, (regardless of the actual number of individual animals comprising the unit, or their actual production span from introduction to removal); e.g., 1 AEU equals 1 head of beef cattle, 0.7 dairy cows (dry), 1.2 horses, 0.18 sheep or goats, 0.25 swine (55 lbs.+), or 820 laying hens or pullets proportionally for 365 days.

Animal Excreta - Solid or liquid animal waste.

Application Interval - The time interval between application of an agricultural input (such as a biological soil amendment of animal origin) to a growing area, and the harvest of covered produce from the growing area where the agricultural input was applied.

B

Bacteriophage - A virus capable of infecting a bacterial cell.

Bedding - Bedding is the preparation of soil by "plowing, blading, or otherwise elevating the surface of flat land into a series of broad, low ridges separated by shallow, parallel channels with positive drainage." Bedding is done to improve the drainage of surface water, decrease soil compaction, and to create a warm, dry planting bed for vegetation establishment. The Bedding practice is generally applied to lands with flat to near flat topography and poorly drained soils.

Biological/Ecological Resource - Includes vegetation, wildlife, protected species, and soils within agricultural and allied lands and adjacent 'off-farm' areas within the U.S. and its territories. Vegetation includes native and non-native plant species, including major agricultural crops, invasive, and noxious plant species. Wildlife species include both native and non-native species.

Biological Fixation - The process whereby a substance is removed from the gaseous or solution phase and incorporated into plant tissue, as in carbon dioxide fixation or nitrogen fixation.

Biological Soil Amendment - Any soil amendment containing biological materials such as humus, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination.

Biological Soil Amendment of Animal Origin - A biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts, or table waste, alone or in combination. The term ''biological soil amendment of animal origin'' does not include any form of human waste.

Biosolids - A primarily organic solid product produced by wastewater treatment processes, also known as "sewage sludge."

C

Calid - Warm or tepid temperature.

Carbon Cycle - The process by which carbon moves between the atmosphere and different reservoirs in the earth.

Carbon Sequestration - The process of capture and long-term storage of atmospheric carbon dioxide (CO_2).

Certifying Agent - An individual or other entity that is accredited by the USDA National Organic Program and who is permitted to certify producers and handlers of agricultural products. According to USDA's Web site there are certifying agents that are USDA-accredited and authorized to certify operations to the USDA organic standards.

Coliphage - A bacteriophage that specifically infects the *Escherichia coli* bacterium.

Colony Forming Unit (CFU) - A measure of viable cells in which a colony represents an aggregate of cells derived from a single progenitor cell.

Co-management - For the purposes of this EIS, co-management means promoting stewardship on the farm, including protecting water and soil quality and conserving wildlife and ecosystem habitat, while balancing food safety and farm productivity goals.

Composting - A process to produce humus in which organic material is decomposed by the actions of microorganisms under conditions for a designated period of time (for example, 3 days) at a designated temperature (thermophilic for example, 131 °F (55 °C)), followed by a curing stage under cooler conditions.

Commingled Raw Agricultural Commodities - Any raw agricultural commodity that is combined or mixed after harvesting but before processing.

Community Supported Agriculture (CSA) Program - A program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season.

Concentrated Animal Feeding Operation (CAFO) - A livestock or poultry feeding and producing facility that (a) confines animals for more than 45 days during a growing season, (b) in an area that does not produce vegetation, and (c) meets certain size thresholds. Three categories of CAFOs are defined by EPA, and determine the conditions and degree to which the facility is regulated by the Clean Water Act, based on Animal Equivalent Units (AEUs) - Large CAFO (1000 or more AEUs), Medium CAFO (999 to 300 AEUs), and Small CAFO (under 300 AEUs). Federal law requires regulated CAFOs to obtain National Pollutant Discharge Elimination Systems permits before they can discharge wastewater from the facility from a delegated state agency or EPA. CAFOs are also potentially subject to regulation under the Clean Air Act if statutory thresholds are exceeded.

Covered Activity - Growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of "farm" as defined in section 112.3 (79 Fed. Reg. 58434 at 58470).

Covered Produce - Produce that is subject to the requirements of proposed 21 CFR part 112 in accordance with §112.1 and 112.2. The term ''covered produce'' refers to the harvestable or harvested part of the crop.

Cultural Resources - Physical evidence or place of past human activity, such as a site, object, landscape, or structure. A site, structure, landscape, object, or natural feature of significance to a group of people traditionally associated with it. Types of cultural resources include archaeological resources, historic structures, cultural landscapes, and museum objects (NPS, 2014).

Curing - The maturation stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition.

D

Direct Water Application Method - Using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food-contact surfaces during use of the water. (Note: By cross-reference to the definition of "covered produce," this term only applies to methods in which the water is intended to, or is likely to, contact the harvestable part of the covered produce).

E

Effectively Treated Biological Soil Amendment of Animal Origin - A Biological Soil Amendment of Animal Origin which has undergone a scientifically valid controlled physical process, chemical process, or combination of physical and chemical processes that satisfies one of the microbial standards for *Listeria monocytogenes, Salmonella*, and *E. coli O157:H7*.

Endangered Species - The term "endangered species" means any species which is in danger of extinction throughout all or a significant portion of its range other than a species of the Class Insecta determined by the Secretary of the Interior to constitute a pest whose protection under the provisions of this Act would present an overwhelming and overriding risk to man (16 U.S.C. § 1532(6)).

Enteric Fermentation - A digestive process by which carbohydrates are broken down by microorganisms into simple molecules for absorption into the bloodstream of a ruminant animal.

Environmental Justice - The fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. It will be achieved when everyone enjoys the same degree of protection from environmental and health hazards and equal access to the decision-making process to have a healthy environment in which to live, learn, and work.
(http://www.epa.gov/environmentaljustice).

Evident Animal Intrusion - Evidence of animal intrusion includes the observation of significant quantities of animals, animal excreta, or crop destruction via grazing.

F

Facility - Any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Non-bottled water

drinking water collection and distribution establishments and their structures are not facilities.

Farm - An establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term "farm" includes establishments that, in addition to these activities: (i) Pack or hold raw agricultural commodities; (ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in subparagraph (iii)(B)(1) of this definition; and (iii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same ownership; or
(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:

(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and
(2) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.

This definition is consistent with the definition of "farm" presented in the supplemental proposed rule (79 Fed. Reg. 58434 at 58470 – 58471).

Federally Recognized Tribe - An American Indian or Alaska Native tribal entity that is recognized as having a government-to-government relationship with the United States, with the responsibilities, powers, limitations, and obligations attached to that designation, and is eligible for funding and services from the Bureau of Indian Affairs. Furthermore, federally recognized tribes are recognized as possessing certain inherent rights of self-government (i.e., tribal sovereignty) and are entitled to receive certain federal benefits, services, and protections because of their special relationship with the United States. At present, there are 566 federally recognized American Indian and Alaska Native tribes and villages (http://www.bia.gov/FAQs).

Fence - A constructed barrier to livestock, wildlife, or people.

Field Residue - Materials left in an agricultural field or orchard after the crop has been harvested. These residues may include stalks, stems, leaves, and seed pods.

Food - Articles used for nutriment (including raw agricultural commodities consumed whole, and ingredients or goods prepared or processed and eaten) or drink for man or other animals, including chewing gum, and articles used for components of any such article. This definition is consistent with section 201(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321(f). "Food" also includes seeds and beans used to grow sprouts (78 Fed. Reg. 3504 at 3631).

Food-Contact Surfaces - Those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations, this includes food-contact surfaces of equipment and tools used during harvest, packing, and holding (78 Fed. Reg. 3504 at 3631).

Food Grains - The small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, cotton seed, and soybeans.

Food Hazard - A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Food Hub - A regional food hub is a business or organization that actively manages the aggregation, distribution, and marketing of source-identified food products primarily from local and regional producers to strengthen their ability to satisfy wholesale, retail, and institutional demand.

Food Safety Hazard - Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

Foodborne Illness Outbreak - The occurrence of two or more cases of a similar illness resulting from the ingestion of a certain food.

G

Geometric Mean - The positive n^{th} root of the product of a set of n numbers, or average (http://dictionary.reference.com/browse/geometric mean).

Groundwater - Water from an underground aquifer that has not been held or conveyed in a manner open to the environment.

H

Hazard - Any biological agent that is reasonably likely to cause illness or injury in the absence of its control (78 Fed. Reg. 3504 at 3631).

Harvesting - Applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on a farm. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering,

washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm are examples of harvesting (79 Fed. Reg. 58434 at 58471).

High - The impact is highly noticeable; the overall effects may be the result of a deliberate requisite shift in management practices, which may cause a major beneficial or adverse consequence.

Holding - The storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food, as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks (79 Fed. Reg. 58434 at 58471).

Humus - A stabilized (i.e., finished) biological soil amendment produced through a controlled composting process.

Hyporheic Zone - The region beneath and alongside a stream bed, where the mixing of shallow groundwater and surface water is widespread.

I

Impaired Surface Water - Waters that are too polluted or otherwise degraded to meet the water quality standards set by states, territories, or authorized tribes. (http://water.epa.gov/lawsregs/lawsguidance/cwa/tmdl).

Indian Tribe - Any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined or established pursuant to the Alaska Native Claims Settlement Act (85 Stat.688) (43 U.S.C. 1601 et seq.), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians (25 U.S.C. § 450b).

J

K

L

M

Manufacturing/processing - Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding (78 Fed. Reg. 3504 at 3631).

Manure - Animal excreta, alone or in combination with litter (such as straw and feathers used for animal bedding) for use as a soil amendment.

Microbial Reduction - A decrease in microbial populations as is necessary to protect public health.

Microorganisms - Yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites, including those species that have public health significance.

Minimal - The impact is detectable, and likely reversible, resulting in minor beneficial or adverse impacts.

Minority Populations - Pursuant to the Council on Environmental Quality's (CEQ) Guidance for Federal Agencies on Key Terms in EO 12898 (CEQ, 1997a), and for the purposes of this Technical Report and the associated EIS, minority populations are comprised of members of the following population groups:

- Black or African American: a person having origins in any of the black racial groups of Africa;
- Hispanic or Latino: a person of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin, regardless of race;
- Asian American: a person having origins in any of the original peoples of the Far East, Southeast Asia or the Indian subcontinent;
- American Indian or Alaskan Native: a person having origins in any of the original people of North America, South America (including Central America), and who maintains cultural identification through tribal affiliation or community recognition; or,
- Native Hawaiian or Other Pacific Islander: a person having origins in any of the original peoples of Hawaii, Guam, Samoa or other Pacific Islands.

Mixed-Type Facility - An establishment that engages in both activities that are exempt from registration under section 415 of the FFDCA and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that grows and harvests crops or raises animals and may conduct other

activities within the farm definition, but also conducts activities that require the establishment to be registered (78 Fed. Reg. 3504 at 3631).

Moderate - The impact is detectible to a greater extent than minimal, but impacts are not persistent or irreversible on the resource area.

Monitor - To conduct a planned sequence of observations or measurements in order to assess whether a process, point, or procedure is under control, and, when applicable, to produce an accurate record of the observation or measurement.

N

Non-Fecal Animal Byproduct - Solid waste (other than manure) that is animal in origin (such as meat, fat, dairy products, eggs, carcasses, blood meal, bone meal, fish meal, shellfish waste (such as crab, shrimp, and lobster waste), fish emulsions, and offal) and is generated by commercial, institutional, or agricultural operations.

O

Operator - A person who operates a farm, either doing the work or making day-to-day decisions about such things as planting, harvesting, feeding, and marketing. The operator may be the owner, a member of the owner's household, a hired manager, a tenant, a renter, or a sharecropper.

P

Packing - Placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act (79 Fed. Reg. 58434 at 58471).

Packaging - (verb) Placing food into a container that directly contacts the food and that the consumer receives (78 Fed. Reg. 3504 at 3631).

Packaging - (noun) Containers used for transporting, holding or marketing of food.

Pathogen - A microorganism of public health significance (79 Fed. Reg. 58434 at 58564).

Pathogen Exposure - An event or occurrence that results in contact of humans with a biological hazard that may create the risk of serious adverse health consequences or death.

Pest - Any objectionable animals or insects including birds, rodents, flies, and larvae.

Pre-Consumer Vegetative Waste - Solid waste that is purely vegetative in origin, not considered yard trash, and derived from commercial, institutional, or agricultural operations without coming in contact with animal products, byproducts or manure, or with an end user (consumer). Pre-consumer vegetative waste includes material generated by farms, packing houses, canning operations, wholesale distribution centers and grocery stores; products that have been removed from their packaging (such as out-of-date juice, vegetables, condiments, and bread); and associated packaging that is vegetative in origin (such as paper or corn-starch based products). Pre-consumer vegetative waste does not include table waste, packaging that has come in contact with materials (such as meat) that are not vegetative in origin, or any waste generated by restaurants.

Processed Food - Any food other than a raw agricultural commodity. Includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling (21 U.S.C. 321).

Produce - Any fruit or vegetable (including mixes of intact fruits and vegetables), including mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and herbs. Produce does not include food grains (78 Fed. Reg. 3504 at 3631).

Production Batch of Sprouts - All sprouts that are started at the same time in a single growing unit (e.g., a single drum or bin, or a single rack of trays that are connected to each other), whether or not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown within a single growing unit).

Protected Species - Plants and animals listed by the federal government as needing protection because of their current status. Includes species listed as either Endangered or Threatened through the Endangered Species Act (16 U.S.C. § 1531 et seq.).

Q

Qualified End-User - (with respect to a food). The consumer of the food, or a restaurant or retail food establishment that is located (i) in the same State as the farm that produced the food, or (ii) not more than 275 miles from such farm (78 Fed. Reg. 3504 at 3632). The term "consumer" does not include a business.

R

Raw Agricultural Commodity - Any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing (78 Fed. Reg. 3504 at 3632).

Reasonably Foreseeable Hazard - A potential biological hazard that may be associated with the farm or the food (78 Fed. Reg. 3504 at 3632).

Restaurant - Consistent with 21 CFR 1.227(b)(10), restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. "Restaurant" does not include

facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers. Restaurants are (i) Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants; and (ii) Pet shelters, kennels, and veterinary facilities in which food is provided to animals.

Retail Food Establishment - An establishment that sells food products directly to consumers as its primary function. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term "consumers" does not include businesses. A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations (21 CFR 1.227 (b)(11)).

Rotational Sequencing - The rotation of crops.

S

Sanitize - To adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Seasonality - Pertaining to or dependent on a particular season. Relating to the period of each year when native and ornamental plants and crops can be grown.

Sewage Sludge Biosolids - The solid or semi-solid residue generated during the treatment of domestic sewage in a treatment works within the meaning of the definition of ‘sewage sludge’ in 40 CFR 503.9(w), which states: “Sewage sludge is solid, semi-solid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes, but is not limited to, domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. Sewage sludge does not include ash generated during the firing of sewage sludge in a sewage sludge incinerator or grit and screenings generated during preliminary treatment of domestic sewage in a treatment works.”

Small Business - A farm, on a rolling basis, where the average annual monetary value of produce (as defined in paragraph (c) of section 112.3) sold during the previous 3-year period is no more than $500,000; and the farm is not a very small business as provided in paragraph (b)(1) of section 112.3 (79 Fed. Reg. 58434 at 58470).

Soil Amendment - Any chemical, biological, or physical material (such as elemental fertilizers, humus, manure, non-fecal animal byproducts, peat moss, perlite, pre-consumer vegetative

waste, sewage sludge biosolids, table waste, agricultural tea and yard trimmings) intentionally added to the soil to improve the chemical or physical condition of soil in relation to plant growth or to improve the capacity of the soil to hold water. Soil amendment also includes growth media that serve as the entire substrate during the growth of covered produce (such as mushrooms and some sprouts).

Spent Sprout Irrigation Water - Water that has been used in the growing of sprouts.

Static Composting - A process to produce humus in which air is introduced into biological material (in a pile (or row) covered with at least 6 inches of insulating material, or in an enclosed vessel) by a mechanism that does not include turning. Examples of structural features for introducing air include embedded perforated pipes and a constructed permanent base that includes aeration slots, as well as passive diffusion and mechanical means (such as blowers that suction air from the composting material or blow air into the composting material using positive pressure).

Statistical Threshold Value (STV) - STV approximates a specified percentile of a distribution, which depends upon the inherent variability of the observations in a sample as well as their central tendency.

Surface Water - All water which is open to the atmosphere and subject to surface runoff, including water obtained from an underground aquifer that is held or conveyed in a manner that is open to the atmosphere, such as in canals, ponds, other surface containment or open conveyances.

T

Table Waste - Any post-consumer food waste, irrespective of whether the source material is animal or vegetative in origin, derived from individuals, institutions, restaurants, retail operations, or other sources where the food has been served to a consumer.

Tailwater - Excess irrigation water that runs off a farm field that may be carrying sediments, nutrients, and agricultural chemicals.

Thermophilic - Relating to or being an organism living at a high temperature.

Threatened Species - Any species which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. (16 U.S.C. § 1532(20)).

Turned Composting - A process to produce humus in which air is introduced into biological material (in a pile, row, or enclosed vessel) by turning on a regular basis. Turning is the process of mechanically mixing biological material that is undergoing a composting process with the specific intention of moving the outer, cooler sections of the material being composted to the inner, hotter sections.

U

Undesirable Microorganism - Includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Upland Wildlife Habitat Management - Upland Wildlife Habitat Management is "creating, maintaining, or enhancing areas to provide food, cover, and habitat connectivity for upland wildlife." This conservation practice is applicable on a land "where the decision maker has identified an objective for conserving a wild animal species, guild, suite or ecosystem and "land within the range of targeted wildlife species and capable of supporting the desired habitat."

V

Vermicompost - Compost generated through the conversion of organic waste by earthworms.

Very Small Business - A farm, on a rolling basis, where the average annual monetary value of produce (as defined in paragraph (c) of section 112.3) sold during the previous 3-year period is no more than $250,000 (79 Fed. Reg. 58434 at 58470).

W

Water Distribution System - A system to carry water from its primary source to its point of use, including pipes, sprinklers, irrigation canals, pumps, valves, storage tanks, reservoirs, meters, and fittings.

Water Rights - The right of a user to use water from a water source, such as a river, stream, pond, or a source of groundwater.

X

Y

Yard Trimmings - Purely vegetative matter resulting from landscaping maintenance or land clearing operations, including materials such as tree and shrub trimmings, grass clippings, palm fronds, trees, tree stumps, untreated lumber, untreated wooden pallets, and associated rocks and soils.

Z

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11.0 Preparers and Reviewers

In accordance with 40 CFR § 1502.17, this chapter includes a list of names and qualifications (including position/title, education, experience, and expertise) of individuals who were primarily responsible for preparing the EIS or significant background papers, including basic components of the statement. Experience is denoted within a range (<5 years; 5-10 years; 10-15 years; 15-20 years; 20-25 years; and 25+ years). The description also identifies the primary role the individual assumed in the preparation of the EIS.

11.1 U.S. Department of Health and Human Services, Food and Drug Administration

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Other team members

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Center for Food Safety and Applied Nutrition, Human Health & Safety
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Experience: 15-20 yrs.
Expertise: Pre-to-Post Harvest Produce Safety
Responsibilities: Support FDA Produce Safety Staff Activities

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Responsibilities: Technical expert

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Expertise: Good Agricultural Practices
Responsibilities: Technical Expert-Biological Soil Amendments

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Expertise: Economics
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Expertise: Food policy and regulations
Responsibilities: Produce Safety regulation

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Responsibilities: Technical expert

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Expertise: Public Health
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Expertise: Food Safety, Regulations, Education and Communication
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11.2 Contractor Team

Lead Environmental Manager / Key Point of Contact

Rick Williams
Program/Project Manager
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BS\ Biology
BS\ Environmental Science/Marine Science
Experience: 15-20 yrs.
Expertise: EIS preparation; NEPA analysis
Responsibilities: Lead Project Manager, Purpose & Need, Environmental Consequences, Quality Assurance

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Other team members

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MDA\ Business Management
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Expertise: NEPA Analysis
Responsibilities: Quality Control

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Responsibilities: Socioeconomics, Environmental Justice

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Responsibilities: Air quality Issues

Katherine Ready
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Responsibilities: Socioeconomics, Environmental Justice

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Expertise: Mapping
Responsibilities: Graphics (GIS)

APPENDIX A

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Illustration Key

Note: The Healthy, Diverse Ecosystems Help Keep Pathogens in Check illustration is not drawn to scale; it serves as a visual summary of the conservation practices and food safety actions used to address food safety referenced in this document. These practices and actions do not provide complete and conclusive protection against food-borne pathogens on a given farm/ranch, and some vegetative conservation practices may attract wildlife that can vector pathogens. When implementing in-field practices to address food safety, one should take into account the conditions present on the farm/ranch and use this information to assess the effectiveness of a given practice in reducing the risk of food-borne pathogen contamination of crops. [Note that this material is presented in its entirety in *A Farmer's Guide to Food Safety and Conservation*, by the Wild Farm Alliance and the Community Alliance with Family Farmers (WFA and CAFF, 2013).]

1. Sun: UV radiation from the sun may inactivate recently deposited pathogens on the surfaces of soil and leaves, as well as in clear water. The sun also facilitates the desiccation of pathogens, which leads to pathogen reduction.
2. Dust from animal activity is reduced with the application of water by sprinklers and with manure harvesting. Reducing emissions and removing manure proactively are cost-effective means of mitigating pathogen transfer.
3. Diversions redirect water running off of confined animal feeding operations to waste treatment and sedimentation lagoons, preventing the movement of waterborne pathogens to nearby farm traffic areas, fields and waterways. Vegetated diversions also intercept organic matter and soil carrying pathogens running off pasture, and divert potentially contaminated water away from specialty crop fields. The diversions slow pathogen dispersal and provide a matrix for beneficial bacteria and protozoa that compete with and consume pathogens. Plants should be selected for low-flow filtering capacity and the ability for high flows to flow through the vegetation. Selection criteria should also consider how well air and sunlight are able to penetrate into the vegetation, as the cool, moist, shaded interior vegetation may provide favorable habitat for pathogen survival. Otherwise additional maintenance will be required that regularly harvests and removes excess vegetation.
4. Waste storage pond temporarily stores waste, such as manure runoff from confined animal feeding operations, thereby reducing pollution potential in the landscape. The waste storage pond should be properly designed and maintained so that it does not overflow. Food safety Good Agricultural Practices (GAPs) recommend that the effluent from the ponds not be used on crops typically eaten raw. Monitoring of animal movement around the pond and between waste handling areas and crop fields should be a scheduled activity.
5. Restored wetlands can considerably reduce pathogen transport by slowing the water, which increases the interaction time, and pro- viding a matrix for beneficial microbes. The diverse plant and microbial community establishes desirable interactions that serve to limit pathogen persistence. Use of vegetation and designs that facilitate slow moving water over long periods in the wetland allow the best chance for pathogen reduction in water draining from the wetland. The vegetation in the wetland may decrease the ability of UV light to reach the pathogens, which may increase survival. However, pathogens may be retained on vegetation. As water

recedes, the pathogens that are retained on the vegetation may be exposed to sunlight and desiccation.

6. Riparian forest buffers are vegetated areas along bodies of surface water, including streams, wetlands and lakes. They may trap wind- borne pathogens on their vegetation and filter waterborne pathogens attached to suspended organic-soil particulates and other solids. The diverse plant and microbial community in the buffers encourages interactions limiting pathogen persistence.
7. Flooded field: Food safety GAPs recommend that crops typically eaten raw are not planted on lands that often flood. If and when a flood occurs, it may take time for pathogens present in the soil to die off. Depending on the frequency of floods, the field could be fallowed for a period, replanted to a cover crop, or possibly, permanently taken out of production with the restoration of riparian habitat.
8. Windbreaks can trap dust containing pathogens and prevent it from entering specialty crop fields. Plants should be selected with foliar and structural characteristics to optimize dust/pathogen interception. If interior vegetation is too dense, it may provide a cooler, moister and shadier environment, which may create a favorable conditions for temporary pathogen survival.
9. Evidence of animal intrusion in a crop field should be monitored. Food safety GAPs recommend that farmers monitor for animal feces and signs of feeding, and when found, a no-harvest buffer is placed around the contaminated source, or other measures are taken to reduce risk of harvesting the contaminated crop. The following considerations all factor into determining the appropriate risk reduction actions taken: the type and number of animals; whether they are present intermittently or continually; if they are there because of food, a movement corridor, or live next to the crop; and if they are seen initially before planting or right before harvesting.
10. Hedgerows may trap waterborne pathogens in their root systems, and wind-borne pathogens on their vegetation. Shaded interior of the vegetation may provide favorable conditions for temporary survival of pathogen if too dense.
11. Irrigation: Food safety GAPs recommend using sources of irrigation water that are adequately free of contamination. Management techniques that promote infiltration of the water into the soil can reduce runoff and may aid in reducing the movement of pathogens al- ready present in the field. Techniques that aid in infiltration include soil quality management that increases porosity and improves structure, and irrigation management that keeps soil from becoming saturated.
12. Sediment basins capture and detain sediment-laden runoff that may contain pathogens. Correctly designed, basins allow sufficient time for the sediment to settle out of the water. With moist, cool conditions, the basin may support the survival of pathogens. Having a sediment basin that dries down as rapidly as possible helps to alleviate these moist conditions and helps reduce pathogen survival. Moist sediment that is removed from the basin and put on cropland should be treated as contaminated and a time period similar to non-composted soil amendments between its application and the next crop’s harvest should be established.

13. Riparian forest root zone: The roots of the riparian forest promote water infiltration and provide biological activity. This helps divert pathogens from surface water, and encourages interactions with other soil microorganisms that can limit pathogen persistence.
14. Stream ecosystem: In a stream ecosystem where diverse microbial communities exist, they are thought to reduce pathogens by com- petition, parasitism, and predation. Clear water allows light to reach pathogens, which can lead to their reduction. Flowing water dilutes pathogen populations. Some algae and protozoa may serve as an alternate host for pathogens, allowing pathogens to survive even when environmental conditions are unfavorable.
15. Diverse microbial populations compete with and consume pathogens in water, soil and on plant surfaces. When diverse microbial populations are present, beneficial microbes compete with pathogens for carbon and nitrogen, while others kill and consume them. Diverse microbial communities in water and on plants also compete for resources and/or consume pathogens. In some instances, biofilms (a matrix of bacteria and carbohydrates) can harbor pathogens.
16. Cover crops: Rotating with cover crops increases soil organic matter and supports soil microbial communities that may aid in suppressing pathogens. Cover crops may also reduce the movement of pathogens in water run-off by trapping pathogens in their roots and leaves. They can be used as part of a 'waiting-period' between events that might pose contamination risk (e.g. grazing, flooding) and the planting of a crop typically eaten raw. Cover crops also reduce open soil, which helps reduce dust transmission problems.
17. Integrated pest management (IPM) of vertebrates such as mice and squirrels can be used as a means of control for pest animals that enter crop fields. Having a few predatory animals, such as hawks or owls, on the farm is less of a risk than numerous prey species. A crop should not be planted directly under a raptor nest box or a roost, so that it is not contaminated with raptor feces. Farm traffic should not carry fecal droppings into the cropped area or equipment and storage yard.
18. Harvesting orchard fruit from the tree, not the ground, is recommended by Food Safety GAPs when it will be consumed fresh. Fallen fruit may have come in contact with animal feces.
19. Field borders can intercept and reduce waterborne pathogens moving in overland flow from the field. This planting encourages infiltration and serves as a buffer between the field and the riparian vegetation.
20. Tree bird roost: Food safety GAPs recommend that a no-harvest zone is established under branches that hang over the field to ensure bird feces will not touch the crop.
21. Wildlife corridors allow wildlife to access resources (water, food and cover) without having to walk across crop fields or leave their preferred habitat.
22. Crop placement: Food safety GAPs recommend that leafy green vegetables or other crops typically eaten raw not be planted near manure stockpiles or composting facilities and windrows, or other areas of contamination, as pathogens may transfer to the field via water or wind.
23. Compost: Properly managed compost windrows heat up to a temperature that results in significant pathogen reduction. Compost itself supports beneficial organisms that compete with, inactivate, and consume pathogens. Compost that has been allowed to be re-

contaminated, or compost that is unfinished could be a source of pathogens; thus, measures should be taken to prevent these below par composts from moving onto adjacent fields through wind or water. For information on proper compost management practices refer to 'Chapter 2: Composting' in Part 637 of the USDA, NRCS National Engineering Handbook.

24. Conservation cover is used to establish and maintain perennial vegetative cover to protect soil and water resources on land retired from agricultural production or on other lands needing permanent protective cover that will not be used for forage production. Perennial plants may trap wind borne pathogens on the vegetation and waterborne pathogens in the root system.

25. Prescribed grazing uses animals to manage vegetation. It also helps to increase water infiltration, reduce runoff and prevent erosion. This aids in stopping the movement of pathogens in water runoff. Grazing animals are a reasonably foreseeable source of pathogens; thus, measures should be taken to prevent pathogens from the animals' feces from moving onto adjacent fields through wind or water.

APPENDIX B

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Irrigation Overview (relative to the Produce Safety Proposed Rule)

Introduction

Irrigation allows some arid land to be cultivated, or in other cases is used to increase yields, reduce risk or to grow crops that would otherwise fail to thrive in a certain environment and/or season, for example due to lack of natural precipitation (CDC, 2009). Irrigation allows a wider variety of crops to thrive in a given region than might otherwise occur from natural precipitation. Water application can not only extend the growing season, but can also be used to protect a crop from a frost/freeze situation in the spring and fall growing seasons. For example, Florida citrus crops are spray irrigated during periods of frost to provide warmth to the tree crops). Protection sprays are also applied as sun or heat protection (for example, this approach is used in apples grown in the Pacific Northwest).

There are situations that promote or preclude irrigation, which depend on regional markets, weather patterns, and other factors. In other words, direct application of agricultural water for irrigation varies in prevalence and is not universally practiced; a lot of farms rely on natural precipitation for growing.

The USDA compiles a Farm and Ranch Irrigation Survey (FRIS) the year following each agricultural census, which are conducted every five years; the latest FRIS was completed in 2008 (USDA NASS, 2008). FRIS provides a significant amount of data regarding irrigated acres and crop types but only limited data in terms of water source and the irrigation application methods.

The states with the largest area of irrigated land are Nebraska, California, Texas, Arkansas, and Idaho (USDA NASS, 2008). Three of these "top five" states include states where FDA has conducted FSMA public outreach.

Agricultural water is defined as water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food-contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce). Water applied in any manner that directly contacts covered produce during or after harvest activities, used to make a treated agricultural tea, used to contact food-contact surfaces, or to make ice that will contact food-contact surfaces, or used for washing hands during and after harvest activities is required to meet the requirement of no detectable generic *E. coli* in 100 ml of water in the PS PR. The PS PR proposes water quality criteria for agricultural water used during growing activities for covered produce. The potential environmental impact of the proposed standard and alternatives are evaluated in the Environmental Impact Statement.

Irrigation by manual labor is not included below as an irrigation method because although this type of irrigation might be practiced on smaller operations, it is assumed those domestic

producers using irrigation by manual labor would likely be very small and, therefore, below the threshold of applicability for the PS PR.

It may not be feasible in all cases to change forms of irrigation as a means of complying with the PS PR, due to specific crop requirements, cost or other factors. For example, certain types of produce require daily direct water application for crop protection from sun/heat damage, and accordingly surface, subsurface drip irrigation, and sub-irrigation alone would not be viable solutions for those types of operations.

Below are common forms of irrigation, explained briefly in the context of the applicability of the PS PR (USGS, 2014c and Walker, 1989).

Most Common Forms of Irrigation in the U.S.

1. SURFACE IRRIGATION

Surface irrigation is practiced for crops where ample water can be obtained upgradient or with pumps and diverted into piping or ditches for distribution onto fields or into channels. It sometimes involves dikes, levees, terraces, and furrows to direct the water and could have an outlet or be as elaborate as a return-loop system that recycles water. Water is introduced onto the field through gated outlets from a ditch or pipe. It is left to flow down the field for a set amount of time. Inherently, under surface irrigation, the upper part of the field is exposed to the irrigation water for a longer time than the lower end. In order to allow ample time for the water at the lower end of the field to infiltrate the soil, the upper end of the field is over-irrigated, while the lower end receives less water than ideal. Thus, efficient surface irrigation is where the water can be rapidly pushed down the field, and the opportunity for infiltration is similar throughout the field.

Many surface irrigation systems are manually controlled, with the irrigator turning the gates of the pumps on or off. There are a wide variety of automation schemes using valves and timers to switch the water from one area to another and decrease the flow as the advancing front of water nears the lower end of the field. Water that exits these systems (excess flow, by design) is referred to as “tailwater” or “runoff.” Tailwater can contain excess nutrients and enteric microbes, especially if farming operations are not managed properly. This can be problematic for downstream users.

Flood systems, one type of surface irrigation, work well on certain crops (e.g., rice, celery, potatoes, barley, sugar beets, onions and hydrophytic produce species) that grow in ponded conditions. However, most crops can be grown under some variety of flood irrigation. Flood irrigation is touted as the preferred option on some crops like onions where the top of the bulb does not get wet from sprinkling, thereby minimizing “neck rot.” This type of rot lowers viable storage time of onions and often lowers the sale price. Many of these systems rely on manual labor for operation and therefore are low in operating costs; however, maintenance costs are still a factor.

Surface irrigation might present some unique challenges for farmers who must comply with the PS PR. If water treatment is necessary, treatment of surface water feeding this type of irrigation system might require a large volume of water to be treated (if the source exceeds the microbial water quality standards established by the PS PR and other options are unable to be applied). Practically, unless the crop demands a high amount of water continuously, a less expensive long-term solution could possibly be to install a different sort of irrigation system that is less water-intensive than to treat large volumes of water. Alternatively, some irrigation systems may warrant a replacement (i.e., ground or another surface) source of water in order to obtain water that may not require treatment prior to application.

		
Level Basin Surface Irrigation	Furrow Irrigation using Siphons	Furrow Irrigation System

2. SPRINKLER IRRIGATION

Sprinkler irrigation is accomplished by placing water under pressure in a piping system and directing the pressurized water through a nozzle. The nozzle could be fixed, spin, or move with an apparatus (e.g., supply pipe). Source water could include surface water, groundwater, or a cistern/tank. Timers, water depth sensors, infrared sensors and soil moisture probes can be used to automate sprinkler irrigation systems or they can be manually controlled at the discretion of the grower.

Systems that rely on machine-driven apparatus have associated operating costs (fixed) and maintenance requirements (variable). Sprinklers that are moved by hand or farm machinery have associated labor and maintenance costs.

If necessary, treatment of water for a sprinkler irrigation system would likely require treatment of a large volume. Practically, it might be a less expensive, long-term solution to install a different type of irrigation system (e.g., drip irrigation) that is less water-intensive than to treat large volumes of water. The need to treat large volumes of water could be mitigated by not using "reclaimed" water (i.e., wastewater treatment plant effluent) and/or recirculated runoff water as sources of irrigation water.

Fixed Overhead and Moving Irrigation Systems

These forms of irrigation rely on overhead fixed piping, or in some cases, wheeled machine-driven mobile applicators that direct their spray downward or outward onto the irrigated crop. There are primarily four types: (1) Center/Central Pivot Irrigation Systems, (2) Lateral Moving Irrigation Systems, (3) Fixed Overhead Systems, and (4) Traveling Gun Systems.

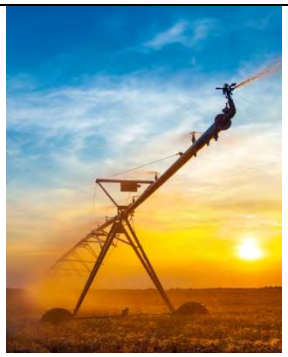
Center Pivot systems, popular in the western U.S. are probably the most commonly recognized type of overhead sprinkler system. Center pivot systems rotate in a circular pattern around a center point and irrigate a circular area. These systems can be overhead on a line that circles the field, or they can be from a central spinning nozzle ejector. Lateral Moving systems can be powered, moved by hand or pulled with farm machinery. Lateral move systems move across the field, either continuously or periodically. A variety of nozzle types can be mounted on the lateral. Overhead irrigation systems effectively mimic the effects of natural precipitation but are fixed in place. Their wetting pattern depends on the overhead track and the types of emitters or sprayheads used, but they are typically designed to wet the full perimeter within the area of coverage. Traveling gun irrigation, self-propelled or continuous, uses a wheeled apparatus with a single rotating sprinkler that expels water as it is moved about on roads between plots. It relies on a delivery line to supply water and is therefore connected to a water source; however, unlike a center pivot system which is fixed to a single water supply, a traveling gun can be moved to different areas.

Traveling Gun System

Two Common Types of Lateral Moving Systems (Gantry Assembly and Wheel Line)

Overhead irrigation can be more uniform than fixed ground sprinklers. In many cases, this is a custom or singly-designed and built system for an individual farm operation. Water could be piped to these systems from a distance, or a source close to the irrigator (such as a well) could be located near the individual or group of applicators. Overhead systems almost exclusively rely on pumping or pressurized water supplies[1] to achieve the necessary head pressure to actuate the sprinkler, although public water supplies are not commonly used due to the associated costs. These systems require either above-ground or in-ground water supply pipes, and in some cases (except where a static upright main is fixed, like in a pivot system) a flexible hose that travels with the gantry sprayer system atop the ground.

[1] It should be noted that information on New England produce farms shows 26% of covered farms (roughly 5,000) use municipal water supplies as their source water.

			
Fixed Big Gun	Fixed Overhead System in greenhouse	Center Pivot System, specifically End Gun	Aerial View of Center Pivot Irrigation

Sprinkler Sprayhead Irrigation

There are a number of types of sprinkler heads that can be used to comprise a sprinkler system. Spray heads are mounted either on the pipe of a center pivot or wheel line, or on tubes that hang closer to the crop. Although there are differences between spray and impact nozzles, and between fixed pattern spray head or spray head mounted on moving machinery, all of these systems are designed to effectively distribute water to the crop.

- *Pop-up*. These are recessed when not in use (below ground level) and actuated by water pressure. There can be a simple circular stationary sprinkler head, or a rotating sprinkler.
- *Rotary*. These can include gear-driven sprinkler, impact sprayers, common "turf rotors" (e.g., golf course sprinklers).
- *Other*. There are also mist sprayers and circular sprayers used in some applications.

The delivery lines of a fixed sprinkler irrigation system are typically installed in a grid pattern underground (at a depth below the plowzone), with the sprinkler heads at intervals allowing a uniform application rate by overlapping the circular patterns. In that arrangement, the edges of the fields could be slightly deprived of water and could be expected to have a lower yield, unless the planting rows were all located within the uniform spray, with some wasted water or conservation cover crops in peripheral edges.

 Impact Sprinkler	 Pop Up (Pressure Actuated) Head	 Impact Sprinkler with Surface Laterals

3. LOW FLOW IRRIGATION METHODS

These systems deliver water directly to the root zone of the crop at or below the soil surface, and the agricultural water may contact the edible portion of root crops that grow below the soil surface. Various types of outlets can be used to achieve this purpose. Timers can be used with these systems, or they can be manually controlled. Low flow irrigation methods include the following types:

- **Bubblers**: These are designed to apply water in small areas, and can be near the soil surface to achieve that effect. This could be achieved with holes in the piping, or permeable materials to permit water to exit under pressure throughout the entire tube.
- **Drip Emitters**: These can be standard, or pressure compensating. Note that there are drip emitters that can be impregnated with EPA registered biocides, and others that can be fitted for backflushing that (along with micron disc filtration) effectively prevent microbes from being released.
- **Subsurface Textile Irrigation**: Although of limited application in commercial situations, this is an underground system that includes an irrigation line (drip tape or drip tube), a subbase impermeable layer, and permeable textile layer that evenly distributes irrigation water (20-30 cm beneath the surface). Subsurface textile irrigation uses capillary action of the soil to allow the water to wick upwards to the root zone.

In terms of the agricultural water standards of the PS PR, except for systems that allow backflushing, it could be difficult to dose underground drip systems with EPA registered biocides without releasing the full volume of biocides into the soil medium. Therefore, treatment of larger volumes of water might be needed to effectively treat these types of systems. However, in contrast, some underground drip emitters are designed to contain EPA registered integral antimicrobial biocides or mechanical means of trapping microbes in the emitter mechanism (removed by backflushing).

The proposed agricultural water requirements only apply to water that is intended to, or likely to, contact the harvestable or harvested portion of covered produce. Therefore, water used in some subsurface and drip irrigation systems used only for the root zone and where the roots are not harvestable or harvested is not covered under the agricultural water requirements of the PS PR.

4. SUB-IRRIGATION

Sub-irrigation is a process very similar in concept to surface irrigation, although water does not reach the surface. In these systems, water is contained by an underground impervious layer and moves upward through capillary forces, unlike in subsurface drip irrigation where water is added within the root zone directly.

In conclusion, certain types of crops benefit from certain types of irrigation systems; not all irrigation systems work interchangeably on every type of crop. For example, overhead spray can be used to protect from frost, whereas surface level irrigation practices (e.g., furrow) would not. Drip irrigation is the most effective sort of application method in arid conditions where water is limited to direct water directly into the root zone to minimize evaporation, whereas other crops grow best in flood cycle conditions (e.g., water chestnuts, watercress, etc.).

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APPENDIX C

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Manure Management Overview

Introduction

The purpose of this memorandum is to provide a broad overview of the use of manure with respect to growing covered produce. The information presented is general in nature; information specific to individual crops, manure types, regional considerations, and best management practices can be obtained through communication with the USDA and local agricultural extension services.

Manure may be defined as animal excreta, alone or in combination with litter (such as straw used for animal bedding and feathers), for use as a soil amendment. Manure is a byproduct of livestock operations and must be appropriately managed and disposed of in order to maintain sanitary conditions. Disposal options include hauling to treatment facilities and/or land application as soil amendments. Green manures are derived from vegetation materials such as yard waste and cover crops and are not considered a potential vehicle for pathogens (when not in contact with, for example, raw manure). Green manures are therefore excluded from this discussion. For the purposes of this discussion, manure and BSAs of animal origin are synonymous.

Beneficial reuse of manure as a soil amendment has been documented worldwide throughout history (University of Illinois Extension, 2014b). Manure is not only a source of nutrients and minerals necessary for plant growth but also adds organic matter that improves soil structure (Schoenau et al., 2006).

Large volumes of untreated (or raw) manure have a likely probability of containing harmful pathogens that could potentially be transmitted to humans via direct contact (University of Wisconsin-Madison Dept. of Dairy Science & The Babcock Institute, 2010; eXtension, 2014). The use of manure-containing soil amendments as an agricultural input increases the likelihood that produce may become contaminated (Jiang and Shepherd, 2009). Soil amendments, partially composted manure, raw manures or teas made from such materials are potentially significant reservoirs of human pathogens. A BSA of animal origin can spread the contamination it harbors to the food it contacts, either directly, or indirectly through contamination of food contact surfaces (Doyle, 2001; and Rangarajan et al., 2000).

Common sources of raw manure include cows (dairy and beef), swine, horses, sheep, goats, and poultry (chickens and turkeys). Nutrient content (concentrations of available nitrogen, phosphorus and potassium) and percent dry matter by weight can vary significantly based on the source (type of animal), whether or not bedding (e.g., straw) is incorporated, how the manure is stored and handled, as well as the method of application (OSU Extension, 2015).

It is important to note that unlike chemical fertilizers, nutrients from raw manure must be transformed from organic to inorganic (soluble/volatile) forms in order to be available for plant uptake (Schoenau et al., 2006). Therefore, treatment technologies such as composting, aerobic and anaerobic digestion are often utilized to accelerate the process. An additional benefit of some of these technologies is that the life cycle of potentially harmful pathogens can be broken, provided that conditions required for survival are not present for a sufficient amount of time.

Proper Manure Application to Land

The proper application of manure is critical for crop productivity and soil health. In determining application rates, timing of application and appropriate methods for application, several factors must be considered. These factors include (but are not limited to) the nutrient content of the manure being applied, available nutrients in the existing soils, and type of crop(s) being grown (nitrogen and phosphorus consumption rates). Such factors also include a variety of site specific conditions such as the potential for runoff or leaching through the soil column (OSU Extension, 2015).

Failure to consider these (and other) factors could result in crop failure, degradation of soil structure, deterioration of surface and groundwater supplies, and other potential broad reaching impacts to our Nation's resources (OSU Extension, 2015). Over-application of manure can compromise the quality of soils; in some cases, salts accumulate in the soils, which is known to negatively impact crop production for several growing seasons (OSU Extension, 2015). Appropriate application can vary significantly from year to year and manure application rates should be determined through laboratory analysis.

Common Manure Handling Systems

Most agricultural manures are stored and applied either in solid or liquid form. Solid manures are typically stockpiled and may or may not be subject to treatment such as composting. Surface application followed by incorporation is typically used for solid manures. Incorporation should occur as soon as possible to minimize nitrogen loss as well as control odors (Colorado State University Extension, 2014).

Liquid manure can be collected as surface runoff in storage ponds or through floor drainage systems (often associated with swine and dairy operations) connected to large storage pits (EPA, 2012d). Liquid manures can either be applied to the surface of the soil (preferably quickly followed by incorporation) or directly injected into the soil (EPA, 2012d). Direct injection of liquid manures not only minimizes loss of nutrients to surface runoff and but also provides effective odor control (EPA, 2012d).

Manure Management Guidance

Across the country, states recognize the value of fertilizing with manure as well as the need to prevent pollution and protect resources. More specific guidance with respect to individual crops, regions and prevailing conditions can be obtained from state and local cooperative extension offices. Table C-1 below provides a list of resources for manure management practices/guidelines.

Table C-1. State-specific manure application resources

State	Resources
Arkansas	Nutrient and Fertilizer Value of Dairy Manure (University of Arkansas Cooperative Extension)
Arizona	http://ag.arizona.edu/animalwaste/farmasyst/awfact8.html
Iowa	Using Manure Nutrients for Crop Production (Cooperative Extension Service, Iowa State University)
Maine	Manure Utilization Guidelines: published by Maine Department of Agriculture; reviewed by University of Maine Cooperative Extension
Michigan	Conservation of Fertilizers and Livestock Manure: Pollution Prevention (National Pollution Prevention Center for Higher Education) Managing Manure in Potato and Vegetable Systems (Michigan State University Extension)

Table C-1. State-specific manure application resources (Continued)

State	Resources
Minnesota	Fertilizing Cropland with Beef Manure (University of Minnesota Extension Service, 2002) Fertilizing Cropland with Poultry Manure (University of Minnesota Extension Service, 1992) Fertilizing Cropland with Swine Manure (University of Minnesota Extension Service, 2002) Land Application of Manure: Minimum State Requirements (Minnesota Pollution Control Agency) Manure Management in Minnesota (University of Minnesota Extension Service, 2012) Self Assessment Worksheets for Manure Management Plans (University of Minnesota Extension Service, 1994) Using Manure and Compost as Nutrient Sources for Fruit and Vegetable Crops (University of Minnesota Extension Service)
North Carolina	Dairy Manure as a Fertilizer Source (North Carolina Cooperative Extension Service) Poultry Manure as a Fertilizer Source (North Carolina Cooperative Extension Service) Swine Manure as a Fertilizer Source (North Carolina Cooperative Extension Service)
Ohio	Estimating Manure Production, Storage Size, and Land Application Area (The Ohio State University Extension) Guidelines for Applying Liquid Animal Manure to Cropland with Subsurface and Surface Drains (The Ohio State University Extension)
Oregon	Annual Manure Application Schedule for Western Oregon (Oregon State University Extension Service) Fertilizing with Biosolids (Pacific Northwest Extension) Manure Application Rates for Forage Production (Oregon State University Extension Service)
South Carolina	Land Application of Animal Manure (Clemson University Extension)
Washington	Farming West of the Cascades: Fertilizing with Manure (Pacific Northwest Extension)
Wisconsin	Guidelines for Applying Manure to Cropland and Pasture in Wisconsin (University of Wisconsin Extension)
All	The following site includes link to map of the US that directs to state specific information: http://www.extension.org/pages/14881/state-specific-manure-nutrient-management-information.

Sources: WCFS (2014); eXtension (2011)

APPENDIX D

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Overview of FDA Tribal Consultation and Outreach regarding the Environmental Impact Statement (EIS)

DATE	ITEM	PARTIES INVOLVED	TOPIC SUMMARY
August 16, 2013	Letter – Initial Invitation to Consultation	FDA; all federally recognized Indian Tribes	Notice to all tribes that the FDA will produce an EIS for the Produce Safety Proposed Rule
September 10, 2013	Letter – Yocha Dehe Wintun Nation to FDA	Yocha Dehe Wintun Nation; FDA	Tribal response to August 16, 2013 letter, accepting invitation for consultation
September 12, 2013	Letter – Invitation to an upcoming FDA tribal webinar consultation	FDA; all federally recognized Indian Tribes	FDA's proposed rule entitled the Preventive Controls for Human Food Proposed Rule and the Produce Safety Proposed Rule, including the FDA's intent to prepare an Environmental Impact Statement
September 23, 2013	Email and Voicemail – Leah Proffitt (FDA) to Yocha Dehe Wintun Tribe	FDA; Yocha Dehe Wintun Nation	Response to September 10, 2013 letter with copy of September 12, 2013 invitation to FDA webinar
October 29, 2013	Letter – Yocha Dehe Wintun Nation to FDA	Yocha Dehe Wintun Nation; FDA	Letter including specific concerns on the proposed rules, and reiterating accepted invitation to consultation
November 5, 2013	Webinar	*FDA Attendees:* • Michael Taylor, Deputy Commissioner for Foods, Office of Foods and Veterinary Medicine (OFVM) • Mary Hitch, FDA • Dan Sepe, FDA • Annette McCarthy, FDA • Ryan Cates, FDA • Jeff Farrar, FDA • Linda Harris, FDA • David Ingram, FDA • Pat Kuntze, FDA • Talia Lindheimer, FDA • Emy Pfeil, FDA • Eric Snellman, FDA • Cynthia Wise, FDA *USDA Attendees:* • Traci Mouw, USDA • Leanne Skelton, USDA	Webinar held in response to request for tribal consultation (from tribal leaders). The purpose of the webinar was to provide more information on the proposed rules and the FDA Food Safety Modernization Act or FSMA.

Overview of FDA Tribal Consultation regarding the Environmental Impact Statement (EIS) (Continued)

DATE	ITEM	PARTIES INVOLVED	TOPIC SUMMARY
November 5, 2013 (Continued)	Webinar	*CDC Attendee:* • Marjorie Santos, CDC *IHS Attendees:* • Debra Grabowski, IHS • Celeste Davis, HIS *Tribal Attendees:* • Adae Romero, (Cochiti Pueblo/Kiowa), LL.M. candidate at University of Arkansas School of Law • Judy Applewhite, Caption Colorado • Les Brown, Columbia River Intertribal • Marsha Whiting, First Nations Development Institute • Ray Foxworth, First Nations Development Institute • Janie Hipp, Indigenous Food and Agriculture Initiative, University of Arkansas School of Law • Peter Matz, Lower Brule Tribe • Colby Druen, National Congress of American Indians • Dineh John, Navajo Agricultural Products Industry • Simon Boyce, Navajo Nation Washington Office • Joanie Buckley, Oneida Tribe • Jeff Mears, Oneida Tribe of Indians of Wisconsin • Mark Kessler, Potawatomi • Danielle Gaines, Reconnecting the Circle • Martha Pearson, Southeast Alaska	Webinar held in response to request for tribal consultation (from tribal leaders). The purpose of the webinar was to provide more information on the proposed rules and the FDA Food Safety Modernization Act or FSMA.
November 14, 2013	Email – Leah Proffitt (FDA) to Samir Assar (FDA)	FDA; Chilkoot Nation	Regarding a message and call with Scott Hansen from the Chilkoot Nation (AK), addressing questions about how the FSMA will affect the Chilkoot Nation

Overview of FDA Tribal Consultation regarding the Environmental Impact Statement (EIS) (Continued)

DATE	ITEM	PARTIES INVOLVED	TOPIC SUMMARY
January 10, 2014	Letter – Invitation to the Annual Tribal Budget Consultation (ATBC) and notice of the 2014 Annual Regional Tribal Consultations	Department of Health and Human Services (HHS); all federally recognized Indian Tribes	Includes a notice to all tribes about the seven upcoming HHS regional tribal consultations occurring between February and April, 2014.
January 17, 2014	Meeting – FDA and Tribal Organizations	*FDA Attendees*: • Michael Taylor, Deputy Commissioner for Foods, Office of Foods and Veterinary Medicine (OFVM) • Rebecca Buckner, Chief Implementation Manager, FSMA, OFVM • Carie Jasperse, Office of the Chief Counsel (OCC) • Ritu Nalubola, Senior Policy Advisor, Office of Policy • Mary Hitch, FDA Tribal Liaison, Office of External Affairs • Laura Pillsbury, Special Assistant to the Deputy Commissioner, OFVM • Felecia Hogue, Executive Secretariat, FVM *USDA Attendees:* • Leanne Skelton, USDA Liaison to FDA for the Produce Safety Rule <u>Via Phone</u>: • Jeff Farrar, Director of Intergovernmental Relations, OFVM • Barbara Cassens, Office of Partnerships, ORA • Kelly Weller, OFVM *Tribal Attendees*: • Brian Howard, National Congress of American Indians (NCAI) • Colby Duren, National Congress of American Indians	Meeting between the FDA Office of Foods and Veterinary Medicine and the Tribal organizations, regarding the FSMA Proposed Rules

Overview of FDA Tribal Consultation regarding the Environmental Impact Statement (EIS) (Continued)

DATE	ITEM	PARTIES INVOLVED	TOPIC SUMMARY
January 17, 2014 (Continued)	• Meeting – FDA and Tribal Organizations	• Simon Boyce, Navajo Nation Washington Office Via Phone: • Janie Hipp, Indigenous Food and Agriculture Initiative, University of Arkansas School of Law • Adae Romero (Cochiti Pueblo/Kiowa), LL.M. candidate at University of Arkansas School of Law • Barbara Rasco, Professor, School of Food Science, Washington State University (works on aquaculture and seafood product development) • Representative from Columbia River Inter-Tribal Fish Commission • Representative from First Nations Development Institute	Meeting between the FDA Office of Foods and Veterinary Medicine and the Tribal organizations, regarding the FSMA Proposed Rules
March 27, 2014	Letter – Invitation to Regional consultation at the Indian Pueblo Cultural Center, New Mexico	FDA; Tribal Organizations in HHS Regions 6 and 7	Invitation to consultation to discuss FDA's FSMA Proposed Rules, including the intent to prepare an EIS.
April 23, 2014	Meeting – Regional consultation at the Indian Pueblo Cultural Center, New Mexico	HHS; FDA; Navajo Nation *HHS/FDA Attendees:* • Michael Taylor, Deputy Commissioner for Foods, Office of Foods and Veterinary Medicine (OFVM) • Rebecca Buckner, FSMA Chief Implementation Manager, FDA • Jeff Farrar, Associate Commissioner for Food Protection, FDA • Latonya Mitchell, Denver District Director, FDA • Lillian Sparks Robinson, Commissioner, Administration for Native Americans *Tribal Attendees:* • Governor Mermejo, Picuris Pueblo • John Shije, Lt. Governor, Pueblo of Santa Clara	FDA's proposed rules required by Food Safety Modernization Act, including intent to prepare an Environmental Impact Statement

Overview of FDA Tribal Consultation regarding the Environmental Impact Statement (EIS) (Continued)

DATE	ITEM	PARTIES INVOLVED	TOPIC SUMMARY
April 23, 2014 (Continued)	Meeting – Regional consultation at the Indian Pueblo Cultural Center, New Mexico	• Tod Robertson, Seminole Nation of Oklahoma • Frances Quintana, Pueblo of Pojoaque • Richard Bernard, Pueblo of Pojoaque • Dolly Naranjo, Pueblo of San Ildefonso • Renae Pablo, Navajo Agricultural Products Industry • Dineh John, Navajo Agricultural Products Industry • Pat Beare, Navajo Pride • Rick Vigil, Former Governor of Pueblo of Tesuque	FDA's proposed rules required by Food Safety Modernization Act, including intent to prepare an Environmental Impact Statement
December 31, 2014	Letter – Notification to Indian Tribes of the publication of the Draft EIS	• FDA; all federally recognized Indian Tribes	FDA invited participation and feedback in commenting on the Draft EIS, and invited participation in a public meeting that was held on February 10, 2015. The Draft EIS was published on FDA's Web site on January 12, 2015. The NOA for the Draft EIS was published in the *Federal Register* on January 14, 2015 (80 Fed. Reg. 1852).

Tribes within the ten HHS Regions that have expressed interest in food safety to the FDA (via consultation requests, participation in outreach such as webinars and conference calls, submission of comments, etc.)

Region I: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

a. Mashantucket Pequot Tribe (Connecticut)
b. Mohegan Tribes of Indians (Connecticut)
c. Mashpee Wampanoag Tribe (Massachusetts)

Region II: New Jersey, New York, Puerto Rico, US Virgin Islands

a. Oneida Nation of New York (New York)

Region III: Delaware, Maryland, Pennsylvania, Virginia, West Virginia

Region IV: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee

a. Seminole Tribe of Florida (Florida)
b. Catawba Indian Tribe (South Carolina)

Region V: Illinois, Indiana, Ohio, Michigan, Minnesota, Wisconsin

a. Saginaw Chippewa (Michigan)
b. Lac du Flambeau Band of Lake Superior Chippewa Tribe (Michigan)
c. Leech Lake Band (Minnesota)
d. Fond du Lac Band (Minnesota)
e. Menominee Indian Tribe (Wisconsin)
f. Oneida Nation of Wisconsin (Wisconsin)
g. Fond du Lac Band (Wisconsin)

Region VI: Arkansas, Louisiana, New Mexico, Oklahoma, Texas

a. Jena Band Choctaw (Louisiana)
b. Pueblo of Cochiti, New Mexico (New Mexico)
c. Pueblo of Laguna (New Mexico)
d. Pueblo of Santa Ana (New Mexico)
e. Pueblo of Taos (New Mexico)
f. Navajo Nation (Arizona, New Mexico, Utah)
g. Choctaw Nation Oklahoma (Oklahoma)
h. Pawnee Nation Oklahoma (Oklahoma)
i. Seminole Nation of Oklahoma (Oklahoma)
j. Muscogee (Creek) Nation (Oklahoma)
k. Absentee-Shawnee Tribe (Oklahoma)

Region VII: Iowa, Kansas, Missouri, Nebraska

Region VIII: Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming

a. Crow Reservation (Montana)
b. Crow Creek Sioux Tribe (South Dakota)
c. Oglala Sioux Tribe of Pine Ridge (South Dakota)
d. Cheyenne River Sioux Tribe (South Dakota)
e. Navajo Nation (Arizona, New Mexico, Utah)

Region IX: Arizona, California, Hawaii, Nevada

a. Gila River Indian Community (Arizona)
b. White Mountain Apache (Arizona)
c. San Carlos Apache Tribe (Arizona)^
d. Navajo Nation (Arizona, New Mexico, Utah)^
e. Lone Band of Miwok Indians (California)
f. Manzanita Band of Diegueno Mission Indians (California)
g. Yocha Dehe Wintun Nation (California)^
h. Chemehuevi Indian Tribe (California)

Region X: Alaska, Idaho, Oregon, Washington

a. Chilkoot Nation of Alaska (Alaska)^
b. Nez Perce Tribe (Idaho)
c. Coeur d' Alene Tribe (Idaho)
d. Crow Cree Band of Umpqua Indians of Oregon (Oregon)
e. Squaxin Tribe of Squaxin Island (Washington)
f. Lummi Nation (Washington)
g. Shoal Bay Tribe (Washington)
h. Confederated Tribes and Band of the Yakama Nation (Washington)
i. Cowlitz Indian Tribe (Washington)

(^) Denotes tribes who have specifically requested consultation with the FDA

APPENDIX E

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This appendix presents a summary of substantive comments that FDA received during the Draft EIS public comment period. FDA received additional comments on issues unrelated to the Draft EIS, such as comments recommending additional test methods FDA should consider developing, or requesting clarification or expressing a position in terms of the requirements of the rule. We will address those comments separately within any final rule that may result. Comments that were relevant to the analysis within the EIS are addressed in this appendix and attached below under the heading, "Substantive Comments Received on the Draft EIS."

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Scope of the EIS: Analysis of Localized/Regional Impacts

Comment: Several comments suggested that FDA did not adequately assess the potential impact of the rule on the human environment. Specifically, comments asserted FDA confined its analysis in the Draft EIS to the regional and national levels and failed to analyze impacts at the local level. Comments stated that the definition of "significantly" in 40 CFR 1508.27, in part, refers to "the affected region, the affected interest, and the locality." Comments asserted FDA was interpreting "significantly" too narrowly without evaluating short-term effects, local effects, and individually insignificant effects that may have a cumulative impact. A comment asserted that sufficient data exist from which FDA could extrapolate local impacts, such as the 2012 Census of Agriculture, state departments of agriculture, not-for-profit organizations, and for-profit groups. Another comment questioned FDA's assertion that only 2.3 percent of farms nationally could switch from untreated BSAs to chemical fertilizers.

Comments stated localized effects include small and very small farms that may impact the environment at the local level or in the aggregate, particularly farms that change crops grown or stop growing crops, or switch from BSA's to chemical fertilizers. A comment questioned the significance of impacts to air quality at the local or regional level. Specifically, the comment questioned FDA's conclusion that a required application interval for BSAs of animal origin would not be significant on the basis that impacts that are potentially related—such as increased storage and transportation of manure, the resulting increase in emissions of particulate matter, greenhouse gases (GHGs), and ozone precursors—are not significant because they would be localized. The comment asserted that FDA impermissibly ignores the potentially significant impacts that could result from the increased storage and transportation of manure and contravenes FDA's obligation to consider local and regional impacts under NEPA. This comment also questioned FDA's conclusion that the cumulative impacts of the rule and the impacts from the biological soil amendment standard would not be significant on the basis that these impacts would not occur on a national scale. The comment stated that FDA's analysis does not account for the fact that BSA users may be regionally or locally concentrated and that the standard could cause a significant local or regional impact. The comment asserted that the cumulative impacts must consider the potential significance of local and regional effects and that FDA improperly limits its definition of significant impacts to those that occur on a national scale. Lastly, a comment asserted that inadequate consideration of "local or regionally-scaled impacts, means the EIS fails to fulfill the requirements of NEPA" and that FDA's determination that an impact is not significant is not supported.

Response: We disagree with the comments that assert the Draft EIS is insufficient to meet our obligations under NEPA. Further, we consider the comments misguided that suggest our determinations of "not significant" can only be supported if local impacts are evaluated. NEPA does not require the agency to gather information on possible localized impacts that may occur before proceeding with a final rule. NEPA obligations are bound by a "rule of reason," and with regard to this EIS, the agency's analysis of national and regional environmental impacts, and where possible, state impacts, is reasonable. *See Natural Resources Defense Council, Inc. v. Morton,* 458 F.2d 827, 837 (D.C. Cir. 1972) (stating NEPA "must be construed in the light of reason if it is not to demand what is, fairly speaking, not meaningfully possible"). For most resource components

evaluated in this EIS, background environmental conditions and data are available to help establish the foundation for potential environmental impacts with respect to the proposed action for covered produce, by region. For certain resource components (*e.g.*, certain aspects of water resources and socioeconomics and environmental justice), sufficient data are available to determine environmental impacts at the state level. However, in contrast to the commenters' assertion, no data or information are available to determine environmental impacts of current farming practices for covered produce at the local level within a state (*see*, *e.g.*, sections 1.9 and 2.4 of the Draft EIS), nor were any provided by the commenters.

Although FDA did not identify any data sources that would be sufficient to support a localized analysis, we agree that in many situations, data do exist for an analysis of regional or state-level impacts. We used these data whenever possible (*see*, *e.g.*, Chapters 4 and 5 of the EIS, which identify specific regions or states that may be impacted by specific provisions, management decisions, and the rule as a whole or cumulatively with past, present and reasonably foreseeable future actions). The geographic scope of the analysis, including the fact that state and regional data were used when available, is discussed in Chapter 1.9 of the EIS. Our analysis uses the best available data from USDA, EPA, and USGS to determine which regions may be most impacted. FDA also relied on the statistical analysis it conducted using a USDA NASS Fruit and Vegetable Agricultural Practices Survey (USDA NASS, 2001), and the most recent agricultural statistics survey (USDA NASS, 2014a) for information on potentially affected produce growing farms as a data source. In addition, FDA through USDA asked a series of questions of the National Association of State Departments of Agriculture (NASDA) to assist on supplying any available data. Therefore, the data used to make its impact assessment in the Draft EIS was the most accurate available at a scale that is reasonable for a nationwide, regional, and where possible, state level of analysis.

The agency has balanced the cost of any uncertainty with respect to local impacts with the need to complete the final rule, a decision well within the agency's discretion under NEPA. *See Andrus v. Alaska,* 580 F.2d 465, 473 (D.C. Cir. 1978) ("[A]gencies may not be precluded from proceeding with particular projects merely because the environmental effects of that project remain to some extent speculative."). In addition, to the extent the comments suggest NEPA requires an analysis at the local level as a "worst case analysis" of potential environmental impacts, should the hypothetical scenarios envisioned by comments be realized at all, NEPA has no such requirement. *Robertson v. Methow Valley Citizens Council,* 490 U.S. 332, 354-56 (1989). Nor does NEPA require a decision-making structure for the Produce Safety Final Rule that includes localized impacts, rather than the national, regional, and where possible, state level of impact analysis that we provided in this EIS (see *Balt. Gas & Elec. Co. v. NRDC,* 462 U.S. 87, 100-01 (1983) (upholding the Nuclear Regulatory Commission decision to evaluate, generically, the environmental effects of the nuclear fuel cycle for nuclear power plants using the "best available information and analysis" as an appropriate "hard look" analysis required by NEPA). The approach we took in this Draft EIS is consistent with our NEPA obligations to take a "hard look" at the environmental impacts of our action.

Moreover, our approach is consistent with the 2014 CEQ guidance "Effective Use of Programmatic NEPA Reviews." (CEQ, 2014a). This guidance provides that a NEPA analysis may

be on a site- or project-specific level or on a broader, programmatic level. Programmatic analyses set out a broad view of environmental impacts or benefits. Such programmatic analyses are appropriate regardless of whether or not there are subsequent tiered analyses. Programmatic NEPA reviews address the general environmental issues relating to broad decisions, such as those establishing policies, plans, programs, or suite of projects, and can effectively frame the scope of subsequent site- and project-specific federal actions. A well-crafted programmatic NEPA review provides the basis for decisions to approve such broad or high-level decisions as identifying geographically bounded areas within which future proposed activities can be taken or identifying broad mitigation and conservation measures that can be applied to subsequent tiered reviews, or used to monitor the impacts of the action and make adjustments to the implementation methods of the decision, if such an action is needed to further minimize potential significant impacts as long as the purpose and need for the action are preserved.

Under the Produce Safety Proposed Rule, if finalized, to the extent a farm petitions for a variance, the agency could evaluate individual localized impacts, as appropriate, based on the best available information and analysis for the particular variance request. This Final EIS will help the petitioner and FDA to enhance our understanding of the geographic-centric "local" impacts.

Further, we disagree to the extent the comments suggest the definition of "significantly" somehow compels us to evaluate the localized environmental impacts in this EIS. The agency has discretion to determine the appropriate scope of review of the EIS; for the produce rule and our regulation of covered produce, we chose appropriately to consider national, regional, and where possible, state environmental impacts based on the best available information. Data and information are not available for us to use to evaluate localized impacts. Such an analysis would be speculative and based on conjecture, and NEPA does not require us to evaluate localized impacts on such grounds. For the reasons set forth above, we are making no changes to the Draft EIS in response to these comments.

With regard to the 2.3 percent statistic, to determine the approximate percentage of covered farmers using untreated BSAs of animal origin, FDA relied on the statistical analysis it conducted using a USDA NASS Fruit and Vegetable Agricultural Practices Survey (USDA NASS, 2001), Fertilizer Use and Price Statistics (USDA ERS, 2013b), and the most recent agricultural statistics survey (USDA NASS, 2014a) for information on potentially affected produce growing farms as a data source. FDA documented its statistical analysis within the PRIA where it determined that approximately 820 farms that grow covered produce use different forms of untreated (raw) manure. FDA, in its Supplemental Notice of Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption - Economic Impact Analysis (a.k.a. supplemental PRIA (FDA, 2014b)), found that an estimated 35,503 farms would be covered by the rule. Thus, 820 farms out of 35,503 farms is approximately 2.3 percent. The makeup of the 820 farms is also documented in Chapter 2.3 of the EIS.

With respect to impacts from the biological soil amendment standard, FDA's proposed rulemaking potentially impacts more than 35,503 farms nationwide. As such, we have determined that the most reasonable approach to assessing the significance of impacts would include a context of nationwide, regional, and, where possible, state-level assessment, consistent with the best

information available. CEQ regulations defining "significantly" provide that when considering context as a means of analyzing significance, significance varies with the setting of the proposed action (40 CFR 1508.27(a)). While impacts "in the locale rather than in the world as a whole" may be appropriate "in the case of a site-specific action," the context of FDA's proposed rulemaking is broader in scope. (40 CFR 1508.27(a)). FDA acknowledges that conditions vary throughout the nation, and as such the intensity of the impact may vary. With respect specifically to BSAs of animal origin, FDA relied on the statistical analysis it conducted using a USDA NASS Fruit and Vegetable Agricultural Practices Survey (USDA NASS, 2001), Fertilizer Use and Price Statistics (USDA ERS, 2013b), and the most recent agricultural statistics survey (USDA NASS, 2014a) for information on potentially affected produce growing farms as a data source. In addition, FDA through USDA asked a series of questions of the National State Departments of Agriculture (NASDA) to assist on supplying any available data, including on the use of BSAs of animal origin. Therefore, the data and information FDA relied on to make its impact assessment in the Draft EIS was the best available information and included national, regional, and, where possible, state level of impact. Consistent with the scope of our analysis, we did not evaluate BSAs of animal origin at a level below what is discussed in the EIS. Moreover, there is no publicly available data accrued on local use of BSAs of animal origin from which a consistent, meaningful, and reasonable impact assessment could be developed.

Water Treatment Technology

Comment: One comment expressed concern that presently there is a lack of information and understanding of what EPA-approved water treatment technologies may be available in the future. The comment states that, as the knowledge on appropriate water testing, pathogen reduction goals, and water treatment options increases, management decisions and their impact on water resources will need further assessment.

Response: We recognize that technology may change in the future in a way that may alter the potential environmental impacts that we set forth in our analysis in the EIS based on currently available data and information. The PS PR would not exclude any water treatment technologies as long as they are effective and satisfy the requirements of § 112.44. As described in the PS PR, any chemicals used in the treatment of water would require EPA registration before they can be lawfully used. We also noted, however, that at the present time, no such registration for chemical treatment of irrigation water exists.

To the extent this comment suggests that we will have a future obligation to consider any environmental impacts that may arise as a result of changes in knowledge relating to appropriate water testing, pathogen reduction goals, and water treatment options, in the absence of a major Federal action undertaken by FDA, this assertion is incorrect. While agencies are required to "prepare supplements to either draft or final environmental impact statements if . . . (ii) There are significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts" (40 CFR 1502.9(c)(1)), "supplementation is required only if 'there remains major Federal actio[n] to occur.'" *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55 (2004) (quoting *Marsh* v. *Oregon Natural Resources Council*, 490 U.S. 360, 385 (1989)). The

availability of additional knowledge relating to appropriate water testing, pathogen reduction goals, and water treatment options does not, without a major Federal action (e.g., a subsequent rulemaking), require further assessment under NEPA.

FDA made no changes to the EIS based upon this comment.

Threshold for Coverage of the Rule Based on Monetary Value of Total Food Sales

Comment: Some commenters expressed concern that the proposed rule would not apply to farms that fall under the limit of $25,000 average annual monetary value of produce sold during the previous 3-year period. Specifically, comments noted that such farms have the potential to sell contaminated produce to a customer base and that FDA should consider the corresponding impacts that the rule may not be effective to protect public health.

Response: FDA has considered the impact to food safety of excluding certain farms based on their annual sales, in both the 2013 proposed rule (78 Fed. Reg. 3504 at 3518) and the 2014 supplemental proposed rule (79 Fed. Reg. at 58437). FDA tentatively determined that farms with annual sales of produce below $25,000 would not contribute significantly to the volume of produce in the marketplace that could become contaminated and, therefore, would have little measurable public health impact. In addition, such farms are and would continue to be covered under the adulteration and other applicable provisions of the FFDCA and applicable implementing regulations, irrespective of whether they are included within the scope of the PS PR.

Moreover, in Chapter 2.2 of this document, we considered alternatives for including farms that sell less than $25,000 average annual sales of produce, using information in FDA's 2013 PRIA (FDA, 2013b). Our analysis indicates that, under the alternative of excluding farms with annual food sales of $10,000 or less, the estimated annual benefits (in healthcare costs avoided) would be very small compared to the overall cost to farms. FDA dismissed this alternative from detailed analysis because the anticipated costs outweigh the potential benefits from eliminating all illnesses associated with these farms. See Chapter 2.2 under the subheading titled *Potential alternatives that were eliminated from further review*, for more discussion on FDA's reasoning for not considering this alternative to be feasible. FDA also considered removing the $25,000 threshold entirely, based upon this commenter's suggestion. FDA does not believe that removing the $25,000 threshold is a reasonable alternative for the same reasons that the $10,000 threshold was dismissed from detailed review in the EIS. We provided our rationale in a new section within Chapter 2.2 under the subheading titled *Potential alternatives from commenters that were eliminated from further review.*

Scope of the EIS: Coverage of Emerging Agricultural Industries Including Urban Agriculture, Re-circulating and Aquaponic Farms

Comment: One commenter requested that the EIS address potential impacts to urban agriculture and re-circulating farms. The commenter suggested that the nature of activities and operations of these farms do not make them subject to the proposed rule, particularly that the provisions of proposed subpart E (proposed §§ 112.41 to 112.50), subpart F (proposed §§ 112.51 to 112.60) and subpart I (proposed §§ 112.81 to 112.84) do not apply to these types of operations. The commenter stated that their operations may rely (in some circumstances) on fish waste fertilizer that is not intended to and is not likely to come into contact with the harvestable portion of covered crops, and these farms may not have inputs from mammalian or avian species that are typically associated with pathogens such as *E. coli* to be introduced to the growing environment, whereas fish and shellfish do not typically host the same pathogens that affect mammals and avian species. The commenter also stated that re-circulating, urban, and/or aquaponic-based farms often use potable water sources (many that are municipally treated) as agricultural water.

The commenter went on to suggest that because urban farms are not specifically represented in the Draft EIS, FDA precluded meaningful analysis of certain farming actions in accordance with 40 CFR § 1502.9(a) and that more discussion of urban agriculture should be included in the Final EIS.

Response: FDA acknowledged the applicability of agricultural water provisions (proposed subpart E) to farms that use re-circulated water within the preamble to the 2013 proposed rule (78 Fed. Reg. 3504, see also proposed § 112.46(a)). Chapter 2.1 subpart E of the EIS addresses the proposed action and alternatives for the quality of water that may affect all farms that are covered under the proposed rule, which is irrespective of the type of operations (i.e., how certain produce is grown) but rather applies to all produce farms that meet the requirements of proposed subpart A (proposed §§ 112.1 – 112.6). The analysis in Chapter 4.2 of the EIS applies to recirculating/aquaponic farm operations. However, if covered produce is grown in an aquaponic system, but the water is not intended to or likely to contact the harvestable portion of the produce being grown, then that water would not be agricultural water under the rule. Given the nature of aquaponic farming, contact with BSAs of animal origin and animals, both domesticated and wild, is unlikely and, therefore, it is anticipated that those provisions would generally not be expected to apply.

With respect to urban agriculture, to the extent that statistics and data are reported within the sources of information that FDA used to evaluate impacts of the rule, e.g., USDA NASS surveys, water availability, the use of BSAs of animal origin versus green manuring and/or chemical fertilizers, then aspects of urban agriculture are evaluated in the EIS. FDA did, therefore, consider urban farming within the level of information assessed. As discussed in Chapter 1.9, urban farms are also included within the geographical scope of the analysis.

FDA made no changes to the EIS based upon this comment.

Cost of Compliance

Comment: Several commenters expressed concern that the cost of compliance with the rule would increase the cost of production, particularly for smaller farms, and that those costs would also result in higher prices to consumers.

Response: With respect to compliance costs for smaller farms, FDA took a number of actions to consider in detail the costs to farms from implementing provisions of the proposed rule and disagrees with the concerns raised by commenters. FDA prepared a PRIA and supplemental PRIA (FDA, 2013b and FDA, 2014b) to assess the costs and benefits of available regulatory alternatives and to select the regulatory approach that maximizes net benefits (including potential economic, environmental, public health and safety effects, distribution impacts, and equity). FDA further proposed certain criteria for when certain businesses may be eligible for a qualified exemption from provisions of the proposed rule, and instead would be subject to certain specified modified requirements (see proposed §§ 112.5 and 112.6). These qualified exemptions are expected to minimize the economic burden for certain qualified small and very small farms. Qualified exemptions are discussed in the EIS in Chapters 1.4 and 2.1 subpart A.

FDA does acknowledge the possibility that the cost of compliance for farms could potentially result in higher produce prices for consumers, as discussed in the PRIA (FDA, 2013b) and in the EIS in the introduction to Chapter 4.3 and within Chapter 4.3.1 (regarding the economic impacts associated with the application interval for subpart F Untreated BSAs of animal origin).

FDA had included discussions of the economic costs of provisions of the proposed rule in the same sections discussing environmental impacts of the Draft EIS but has revised the Final EIS to remove those discussions of economic costs. FDA addressed costs of the PS PR (including to consumers, and in accordance with Executive Orders 13563 and 12866) in its 2013 PRIA (FDA, 2013a) and the supplemental PRIA (FDA, 2013b). However, with respect to produce commodity prices that could potentially be affected by certain application intervals for BSAs of animal origin (see Chapter 4.3.1, Alternatives I, IV, and V), we maintain that while commodity prices could increase resulting from a decrease in supply in any particular region, the demand for a certain produce commodity would eventually be met by other growers in the region, growers in other regions (commodity and environment specific), or international suppliers, thereby stabilizing any commodity price increases.

Socioeconomic Impacts and Imported Produce

Comment: Some commenters expressed concern that there would be socioeconomic impacts to U.S.-based farms from importing more produce.

Response: It is not clear, nor did the comments explain, why an increase in imported produce, should it occur as a result of the rule, would result in socioeconomic impacts to US –based farms. Management decisions made by U.S.-based, covered farms, such as choosing to grow non-covered produce or going out of business, may result in some portion of farmers reducing the number of crop rotations within a year, which could reduce the amount of produce grown; however, any such

reduction would be expected to be stabilized by market forces. This may open portions of the market such that an increase in importations of foreign produce may be anticipated, but any such gaps may also be filled by other growers, regionally or locally. These socioeconomic impacts are considered in Chapter 4 of the EIS as part of the analysis of the potential impacts of the management decisions.

FDA made no changes to the EIS based upon this comment.

Assessment of Management Decisions

Comment: One commenter challenged our conclusion regarding the likelihood of a management decision to stop growing a covered crop and switch to crops that are not covered by the rule. The commenter suggested that a more likely management decision, particularly for smaller farms that specialize in heirloom varieties of vegetables, would be to stop farming altogether. The commenter further suggested that FDA should evaluate management decisions for small farms to consolidate their farmland into larger operations; to sell their farmland for development (unspecified type of development); or to switch crops to corn or soybeans and take a harder look at the impacts to soils and for increased water consumption associated with those types of crops.

Another commenter stated that FDA provided no basis for concluding that the ability of a farmer to switch water sources or choose methods to allow for microbial die-off would mean that farmers would choose such alternative strategies and why doing so would mitigate impacts from increased chemical treatment, thereby further asserting that FDA did not account for all possible management decisions available to farmers.

Response: FDA relied on information provided through extensive public outreach conducted through FSMA stakeholder engagement, scoping for the EIS, comments provided on the 2014 supplemental proposed rule (79 Fed. Reg. 58434), and through direct consultation with USDA when developing the potential management decisions that farmers may make when attempting to comply with the proposed rule, and the relative likelihood that each management decision would be chosen.[1] Chapter 2.1 discusses the reasoning behind the management decisions assessed for each potentially significant provision. Based upon the outreach FDA conducted on the proposed rule, FDA assessed the potential for such actions as switching to non-covered crops or to cease growing produce altogether. These management decisions are qualitatively assessed in Chapters 4.2, 4.3, 4.4, and 4.7.

As discussed in Chapter 4.2 (see additional analysis under the management decision to cease growing covered produce) and Chapter 4.7, a management decision to cease growing covered produce could be made by certain very small farms or livestock operations that grow small amounts of produce; many such diversified farming-livestock operations would likely be excluded based on the proposed monetary threshold of $25,000 of annual sales of produce (proposed 21 CFR 112.3(c)). Large operations would likely not cease production of covered produce and would

[1] For information on scoping and public comments, refer to Chapter 1.8 FSMA stakeholder engagement.

choose another mechanism for addressing the proposed produce safety standards because large farms could absorb the costs associated with compliance of the rule.

The EIS acknowledges in Chapter 1.9 that management decisions that a grower may take if the PS PR is finalized would rely on a broad number of factors, including, but not limited to, availability of "safe" water or an alternative "safe" water supply (including ability to apply the flexibility options provided in the PS PR) and the costs associated with accessing the water, availability and costs associated with soil amendments, the extent to which grazing animals or wildlife may contaminate covered produce, climate and weather, soil quality conditions, topography, demand and prices for certain agricultural commodities, and the type of crop being grown. These conditions vary widely across the nation and often are specific to the location of the farm and the grower. The crops, soil conditions, water supplies, and management techniques used on one farm may not be the same conditions found on a neighboring farm or other farms in the same county.

FDA does not agree with the commenters that it is reasonable to believe that enough farms would make the same management decision, such as to cease farming or to switch to non-covered produce, to the extent that would rise to a significant impact on a regional or national level. Moreover, commenters provided no information regarding the basis for their assertion that farms may change any business practices, nor to support the assertion that specialized farms would be unable or unwilling to adapt to other crops. Recent events, such as the prolonged drought in California, have shown that farmers will adapt their business practices for a variety of reasons. These can include reduced water availability, reduced demand, or crop disease, amongst others. Chapter 4.2's discussion of management decisions addressing "*Switching water source"* and "*Switching the irrigation method to a non-contact method*" specifically addresses water conservation practices that many farmers are practicing in terms of employing drip and low-flow irrigation technologies as a means of adapting to drought conditions across different regions of the nation. Moreover, even if we know a particular grower's plan, our analysis in this EIS is not at a local level.

FDA made no changes to the EIS based upon this comment.

Socioeconomic Impacts: Low-Income Operators

Comment: One commenter states that relying on a median value of income that is higher than the national poverty line does not mean that there are no low-income farms. The comment stated that household income may include income from off-farm jobs that subsidize farm operations. The comment cited to data from the USDA's Agricultural Resource Management Survey from 2013 that showed farms with negative returns. The comment indicated the calculations in the Draft EIS are not appropriate to view how costs of the regulation may be absorbed.

Response: We agree with the assertion in this comment that relying on a median value of income that is higher than the national poverty line does not mean that there are no low-income farms. We also recognize that household income may include income from off-farm jobs that subsidize farm operation and that USDA's Agricultural Resource Management Survey from 2013 shows some

farms with negative returns. Such facts are inapposite to our analysis, however, and we disagree that the numbers in the Draft EIS are not appropriate to view how costs of the regulation may be absorbed.

In conducting the Environmental Justice analysis, FDA determined that low-income populations—those that may be disproportionately affected by the PS PR, if finalized—include any persons whose median household income is at or below the 2012 HHS poverty guidelines (see 77 Fed. Reg. 4034, January 26, 2012). In addition to the 2012 poverty guidelines, FDA used the USDA Agricultural Resource Management Survey data sheet, *Principal farm operator household finances, by ERS farm typology* (USDA ERS, 2012b; hereinafter "USDA ERS data") to determine low-income populations for purposes of this EIS. The HHS poverty guidelines are a simplified version of the USCB poverty thresholds based on median household income. While the HHS poverty guidelines do not distinguish between farm and non-farm families, the USDA ERS data does have income-based information that is specific to farms. Since each of these sources reports information based on median household income, which is common comparable data between farming and the overall national poverty level, FDA used the HHS guideline and the USDA ERS data to determine whether and where, on a nationwide/regional level, the PS PR would affect low-income populations. Since the USDA NASS 2012 survey was a major information source for the EIS, the 2012 data from the HHS guidelines and the 2012 USDA ERS median farm operator level was also used as a means of achieving the most accurate comparison. While it is true that the USDA ERS number is an average of the farm and off-farm household incomes of residence farms, intermediate farms, and commercial farms, FDA feels that based on its research and the national/regional scope of the EIS, this number serves as an appropriate number to use in order to determine whether there are low-income farm operators that could be impacted by the PS PR. As stated in the EIS, the poverty guideline for a family of four in 2012 was set at $23,050, and the USDA ERS data shows a median farm operator household income in 2012 of $68,298. This exceeds the $23,050 guideline as well as all other 2012 HHS poverty guidelines for families up to eight members (see Table 3.7-17 in the EIS). While FDA acknowledges that there still may be low-income principal operators that may be adversely impacted by the costs associated with the rule, based on the aforementioned available information, we cannot reasonably identify low-income populations on a national or regional level that could be affected by the PS PR.

Marketing Agreements

Comment: One commenter expressed concern that the Draft EIS made assumptions that because the majority of covered produce may be produced under some sort of marketing agreement (primarily comprised of larger farms), and because many marketing agreements may have similar standards as what is proposed by FDA, that the majority of farms are growing produce under marketing agreements and, therefore, there will be limited impacts from the new proposed standards. The commenter suggested this conclusion may be inaccurate and asserted that the severity of potential impacts from the rule may be greater than the impacts assessed in the EIS. As an example, the commenter questioned whether FDA consulted the USDA's National Organic Program for more relevant statistics.

Response: The commenter mischaracterizes FDA's approach to assessing impacts to farms by overstating our reliance on marketing agreements as a means of minimizing significance. Marketing agreements do help to form the background conditions that many farms potentially covered by the rule are already experiencing. Many marketing agreements are voluntary programs with standards (similar to what FDA proposes) that are mandatory for those who choose to participate in that program. Some marketing agreements, e.g., T-GAPs, are mandatory for growers of certain commodities in specific states. FDA presents certain examples of marketing agreements in Tables 2.1-1 (Chapter 2) and 5.3-1 (Chapter 5); however, these are few agreements among many. Whether voluntary or mandatory, marketing agreements are an important factor in considering impacts to farms that grow produce because many farms that would be covered under the rule do participate in various types of marketing agreements. Furthermore, FDA does not solely rely on the existence of marketing agreements to determine impacts related to the rule. For example, in Chapter 4.2, the EIS specifically identifies certain regions where switching water sources are more likely to occur (based on water use and availability data provided in Chapter 3.1), and the regions discussed include Regions B, C, D, I, J, and U, despite the fact that most covered produce grown in these regions are also subject to marketing agreements. As identified by the EIS these regions grow the majority of produce consumed in the nation. Factors other than the marketing agreements are acknowledged as potentially playing a role in minimizing the impacts; for example, the alternatives analysis in Chapter 4.2.1 also attributes impact minimization to the added flexibility that accounts for microbial die-off under subpart E Alternative I. Under Alternative II, by comparison, the potential impacts are not minimized at all by the existence of marketing agreements. Therefore, no impact assessment in Chapter 4 solely relies on the existence of marketing agreements to minimize the severity of potential impacts.

With respect to consultation with USDA's National Organic Program, Chapter 1.8 identifies that USDA was a cooperating agency in preparing the EIS and that within the USDA, FDA specifically consulted with representatives of USDA, USDA NRCS, and USDA AMS, which oversees the National Organic Program. The USDA ERS was also consulted in the preparation of the PRIA. FDA conducted an extensive analysis of potentially affected farms using data provided in part by USDA surveys, including NASS surveys, a National Organic Survey, and specially conducted surveys that are not typically repeated (surveys identified in Chapters 1.7, 1.9, 2.1, and throughout Chapter 3). FDA's original estimates are found in its PRIA (FDA, 2013b).

FDA made no changes to the EIS based upon this comment.

Prospective Farmers

Comment: One comment stated that FDA does not consider potential impacts to prospective farmers. The comment asserted that the cost of compliance with the Produce Safety Rule may deter prospective farmers from deciding to grow covered produce and explained this may be particularly problematic in light of the aging farm population and recent decline in younger entrants into the market.

Response: FDA introduces in Chapter 1.9 a discussion on the general decline in farming, which has been occurring for several decades and for many reasons that are beyond the scope of this EIS. FDA further discusses the trend analysis of prospective farmers in Chapter 3.7.1 (Tables 3.7-4 and 3.7-5, and under the subheading "Beginning Farmers"). The tabular data shows a current and ongoing decline in younger principal operators beginning a business, demonstrating that existing trends are already downward. Since the publication of the Draft EIS, FDA has evaluated further the available data and trends discussed in the sections described above to determine if it was possible to identify any impacts on prospective farmers from similar actions such as the implementation of voluntary or mandatory marketing agreements. In the course of this further evaluation, FDA reviewed (1) USDA AMS's *Federal Register* notice from April 2011 that described the material issues raised at public hearings as well as the arguments contained in the post-hearing briefs held over the proposed national marketing agreement regulating leafy green vegetables (76 Fed. Reg. 24292), (2) the initial USDA AMS *Federal Register* publication announcing the public hearings noted in (1) that discussed the reasons why numerous members of the fresh produce industry petitioned USDA AMS to hold the hearings (74 Fed. Reg. 45565, September 3, 2009), and (3) the University of California Agriculture and Natural Resources Division's, *UC Small Farm Program Research Brief: Grower's Compliance Costs for the Leafy Greens Marketing Agreement and Other Food Safety Programs* (Hardesty and Kusunose, 2009). Following this additional evaluation, FDA has determined that the data do not show that the introduction of marketing agreements with similar requirements exacerbate the current rate of decline in younger principal operators beginning a business. In fact, none of the documents, such as the examples provided above, discussed issues involving prospective farmers being deterred from entering farming in light of pending or in place marketing agreements with similar requirements as the PS PR. Therefore, we are aware of no data or information, nor did the comment provide any, to support the assertion that the PS PR would deter prospective farmers from growing produce. FDA made no changes to the EIS as a result of this comment.

Microbial Quality Standard

Comment: One commenter stated that FDA did not consider an alternative set forth in the scoping and rulemaking comments requesting that FDA analyze the environmental impacts of developing a microbial water quality standard for agricultural water. The commenter asserted that FDA instead adopted EPA's recreational water standard, to which it expressed opposition. The commenter recommended that FDA develop an appropriately flexible and risk- and science-based standard for agricultural water. The commenter further stated that developing a microbial water quality standard would significantly reduce the likelihood that the PS PR will have negative impacts on the environment for two reasons: (1) a flexible, region-specific standard that is developed for agricultural water is likely to affect less farmers and would allow those farmers that are affected to avoid more extreme or expensive management decisions to achieve compliance; and (2) such a standard would permit farmers to consider their local environments in determining the best manner to keep agricultural water safe, which would be less likely to result in farmers pursuing environmentally harmful measures. Additionally, the commenter asserted that a microbial water quality standard is likely to have fewer impacts for human health and safety, as fewer agricultural workers will be exposed to harmful chemicals, and likely to be less expensive.

Response: FDA explained the scientific rationale for the proposed microbial water quality standard, including our review of the EPA recreational water quality criteria (RWQC), in the supplemental proposed rule (79 Fed. Reg. at 58443 through 58444). As explained in that document, FDA considered the EPA RWQC and the WHO recommendations to propose an approach that provides a generally applicable microbial level for all agricultural water and also provides for flexibility in order to account for the wide range of irrigation water sources, irrigation practices in different regions of the country, and different types of crops. We used the EPA RWQC as the starting point for a quantitative microbial water quality standard for water that is used for growing of produce (other than sprouts) in a direct application method in proposed § 112.44(c) (with additional provisions in proposed §§ 112.44(c)(1) and (c)(2)). A majority of the concerns with using the RWQC appeared to center around the need to account for circumstances that are unique to produce growing and irrigation, such as die-off after application, which are factors that would not have been accounted for in formulating water quality requirements for recreational water purposes. FDA acknowledged these shortcomings, and proposed a scheme that incorporates additional flexibility and provides means to achieve the proposed microbial quality standard for agricultural water used for direct application during growing, *i.e.,* by either applying a time interval (in days) between last irrigation and harvest using a microbial die-off rate of 0.5 log per day (proposed § 112.44(c)(1)); and/or applying a time interval (in days) between harvest and end of storage (including during activities such as commercial washing) using appropriate microbial die-off or removal rates, provided there is adequate supporting scientific data and information (proposed § 112.44(c)(2)). In addition, under proposed §§ 112.44(d)(1) and (d)(2), FDA proposed to allow use of alternative microbial quality standard and an alternative microbial die-off rate (in lieu of the FDA-established standard or die-off rate), respectively, provided the requirements in proposed § 112.12 are met. FDA also stated its belief that the complete set of amendments to originally proposed § 112.44(c), including the new proposed provisions in paragraphs (c)(1) and (c)(2), address the concerns raised in public comments on the original proposed § 112.44(c).

Likewise, we believe the new proposed provisions in §§ 112.44(c)(1), (c)(2)), (d)(1), and (d)(2) address this commenter's concern about flexibility for farmers in making decisions related to their water quality considering their regional or local growing conditions and farm-specific practices. Chapter 2.1 subpart E Alternative I assesses the impacts of the proposed microbial quality standard of an STV not exceeding 410 CFU of generic *E. coli* per 100 ml of water and a GM not exceeding 126 CFU of generic *E. coli* per 100 ml of water, with the flexibility for farmers to achieve the proposed standard by applying either a time interval between last irrigation and harvest using a microbial die-off rate of 0.5 log per day and/or a time interval between harvest and end of storage using an appropriate microbial die-off or removal rates, including during activities such as commercial washing. As assessed in Chapters 4.2.1 and 4.7, the added flexibility of subpart E Alternative I, over Alternative II, which was the originally proposed standard in the 2013 proposed rule, would provide farmers additional means by which to achieve compliance with the microbial water quality standard, without necessarily having to switch water sources or to chemically treat their water source. FDA continues to find that the EPA generic *E. coli* criteria for recreational water quality provides a quantitative microbial standard that is generally applicable to minimize the risk of known or reasonably foreseeable hazards associated with the use of agricultural water on produce (other than sprouts) during growing in a direct water application method. Further, the

EPA analysis supporting its recreational water quality standard, while not specifically tailored for our purposes, was developed using the necessary scientific rigor and describes illness rates due to incidental ingestion that can be generalized across different bodies of water. We understand that there are circumstances that are unique to produce growing and irrigation, such as die-off after application, which are factors that would not have been accounted for in formulating water quality requirements for recreational water purposes. We acknowledge these shortcomings, but we also believe that our complete set of amendments to proposed § 112.44(c), including new provisions in paragraphs (c)(1) and (c)(2), address these concerns

Drip-Irrigated Root Crops

Comment: Several comments suggested confusion over impacts related to root crop irrigation. Specifically, one comment stated that FDA did not take a hard look at the impacts of an alternative agricultural water standard that includes drip-irrigated root crops. The comment recommended that FDA look closely at the direct, indirect, and cumulative impacts caused by farmers changing irrigation water sources or increasing chemical treatment of agricultural water to comply with the water standard.

Response: FDA agrees with the commenters that whether and how we considered drip-irrigated root crops in our analysis of different alternatives described in the Draft EIS could be clearer. Chapter 2.1 subpart E within the Final EIS has been revised to provide clarity on this issue. The analyses of agricultural water standards Alternatives I through III assume that agricultural water applied using direct water application methods would not be in direct contact with covered crops unless the harvestable or harvested portion of the crop was above the soil surface to some extent, e.g., carrots, where a portion of the vegetable and the edible greens would be above the surface. Alternative IV now contains subalternatives IV-a through IV-c which are the Alternatives I through III expanded to include root crops that are irrigated using low-flow methods, such as drip irrigation where contact is intended to, or likely to, occur with the harvestable or harvested portion of the crop below the soil.

FDA does not agree with the assertion that we failed to take a hard look at the impacts resulting from the inclusion of drip-irrigated root crops. As part of its analysis, FDA did consider the direct, indirect and cumulative impacts caused by farmers making a number of management decisions, including changing the irrigation water source or increased use of chemical treatments, in order to comply with the water standard in Chapter 4.2. Therefore, while there would be an increase in impacts as acknowledged in Chapter 4.2, they are not expected to be significant for any of the sub-alternatives.

The inclusion of water in contact with the harvestable portion of the crop below the soil surface would also result in a minimal change in cost, which is a factor that FDA will consider when preparing the ROD.

Water Sources

Comment: Some comments stated that FDA did not consider potential environmental impacts from farmers switching to municipal water. One comment stated that sprout growers already use municipal water to conduct agricultural activity and that, given the scarcity of surface and groundwater supplies, it is reasonably foreseeable that some farmers could choose to switch to municipal water.

Response: We disagree that FDA did not consider potential environmental impacts from farmers switching to municipal water and that switching to municipal water is a reasonably foreseeable management decision. In concluding that such a management decision is not reasonably foreseeable, we based our determination, in part, on our consideration of an alternative that we eliminated from detailed review: i.e., to establish a water quality standard of no detectible *E. coli* per 100 ml (see Chapter 2.2 under the subheading, *Potential alternatives that were eliminated from further review*, option six). Similarly, we consider any management decision for covered farms to switch to municipally treated systems to be not reasonably foreseeable. With the exception of sprout growers, in areas where surface and groundwater supplies are scarce, where a management decision to switch to municipal water would theoretically be a likely consideration, many farms do not have access to municipal (treated) water due to lack of adequate municipal infrastructure in the rural to suburban areas where most farms are located.[2] A notable exception is California's central valley where water is supplied to farms from a municipal authority (water diversion through canals). Such a canal system is not available in many regions of the United States. Even where it may be theoretically possible to access municipal systems, the capacity of these systems can be a limiting factor that prevents farmers from accessing this water. Where access is available, water availability is a limiting factor. For example, in California, in recent years only 15 to 20% of agricultural water requests for municipal water have been approved (http://www.scpr.org/news/2015/04/02/50747/california-drought-restrictions-faq-what-the-gover/). Therefore, we do not consider switch to groundwater by farmers to be a reasonably foreseeable management decision.

FDA made no changes to the EIS based upon this comment.

Untreated Biological Soil Amendments of Animal Origin

Comment: We received several comments on FDA's standards for the application of biological soil amendments. Specifically, commenters asserted that the FDA did not consider an alternative set forth in the scoping and rulemaking comments requesting that FDA analyze the environmental impacts of developing a manure standard that accounts for application of biological soil amendments that fall between fresh manure and composted material, such as the application of aged manures. These comments asserted that FDA should consider the impacts of an alternative under which a more flexible manure standard would be established to account for the risks created by passive composting methods, which would reduce environmental impacts to water, soil,

[2] Note that in Chapter 2.2 under the subheading, *Proposed Standards dismissed from detailed analysis*, FDA found that only approximately 67 percent of sprouting operations use municipal water.

biological and ecological resources, waste disposal, and air, as well as alleviate some of the pressure on farmers to store or dispose of manure.

Mostly commenters were in favor of USDA's organic regulations that established a 120-day interval between the application of raw manure for crops in contact with the soil, and 90-days for crops not in contact with the soil. Some commenters, however, argued that the organic regulations do not necessarily improve food safety.

Response: The purpose of the proposed rule is to establish science-based minimum standards to minimize the risk of serious adverse health consequences or death. All reasonable alternatives must meet the purpose of the FDA's proposed action. FDA considers "aged manure" and "agricultural tea" to be untreated BSAs of animal origin (Chapter 3.4). FDA's Draft Qualitative Assessment of Risk assessed hazards associated with several on-farm pathways for pathogenic transport, relative to soil amendment use. As assessed in FDA's Draft QAR and reiterated in the EIS (Chapter 3.4), "untreated/raw; partially treated; re-contaminated" BSAs of animal origin have been shown to have the greatest likelihood of being contaminated with pathogens of public health concern. Therefore, FDA does not believe that a more flexible standard for biological soil amendments that may still result in a greater likelihood of pathogen transport to be a reasonable alternative that meets the purpose and need of the proposed action. We revised the EIS in Chapter 2.2 to address the commenter's proposed alternative and our rationale for eliminating the alternative from further review.

In response to other suggested alternatives regarding standard flexibility, FDA acknowledges in Chapter 2.1 subpart F of the EIS that, as indicated in the supplemental notice, FDA will defer its decision on an appropriate minimum application interval until it pursues certain actions, including a robust research agenda, risk assessment, and efforts to support compost infrastructure development, in concert with USDA and other stakeholders. At that time, it may be necessary to either update the ROD, or prepare a NEPA re-evaluation or supplemental statement in accordance with 40 CFR § 1502.9(c), based on FDA's findings.

Chemical Fertilizers

Comment: One comment expressed concerns that the use of chemicals, as opposed to natural fertilizers (e.g., manure), has negative ramifications in that it can cause farming to be more difficult and costly and is often ineffective and harmful to the surrounding land, flora and fauna. In addition to the concerns with the manure and compost regulations, another commenter stated that FDA did not consider that there may be procedural burdens (handling, storage and recordkeeping requirements) to farms currently using treated BSAs that may result in these farms switching to chemical fertilizers.

The comments asserted that FDA needs to reexamine the potential environmental impacts associated with an increase in commercial fertilizer use, as well as for the potential for farms to limit diversification of farming activities that would include livestock.

Response: With respect to the assertion that chemical fertilizers are often ineffective, FDA does not evaluate the effectiveness of such products for agriculture. We do acknowledge that chemical fertilizers are widely used. As we discuss in Chapter 2.1 of the EIS, only an estimated 4,438 covered farms use BSAs of animal origin. The remaining 31,065 farms may already be using chemical fertilizers to augment their soil quality with nutrients. FDA evaluated the potential impacts to soils and biological and ecological resources (including flora and fauna under the terms vegetation and wildlife, respectively) in Chapters 4.3, 4.4, and 4.7. We assessed that chemical fertilizers may enter receiving waters via runoff, and the excess nutrients may cause algal blooms, which may result in eutrophication or otherwise may result in toxic conditions to aquatic organisms. Under any alternative where chemical fertilizers may be used, given the small number of farms that use untreated BSAs of animal origin (estimated at 821 covered farms, or 2.3 percent of covered farms nationally) that could possibly switch to chemical fertilizers, we do not expect the overall impacts to the environment to be significant at a regional or national level. In fact, the 821 farms that could possibly make a switch to chemical fertilizers represent approximately 0.04 percent of all 2,109,303 farms nationwide. Moreover, with proper nutrient management, e.g., proper storage, adherence to state-required nutrient management plans, careful selection of application methods, and use of chemical fertilizers according to their label requirements, we would expect any changes to water quality from their use to be limited and that water quality would return to ambient conditions.

Further, we are not aware of any data or information to support the comments' suggestion, nor did the comment provide any, that farms would limit diversification of their farming activities that would include livestock. There may be a number of reasons, separate and distinct from the rule, that may influence a farmer's decision on how to manage a farm (staffing and monetary resources, etc.).

FDA estimated in its PRIA (FDA, 2013b) the average time and cost per farm to conduct recordkeeping of its activities for applying treated biological soil amendments of animal origin to their crops that were supplied from (1) a third party vendor or (2) using an on-farm process to treat the manure prior to application. These estimates, which are based on the agency's *Evaluation of Recordkeeping Costs for Food Manufacturers* (FDA and ERG, 2007)[3], demonstrate that the time in labor for a farmer to request a Certificate of Conformance, or comparable documentation that satisfies the requirements under § 112.60(b)(1), would be negligible (likely under 0.5 hours). Such documents are commonly requested from vendors. In terms of labor associated with recordkeeping for an on-farm managed process to treat manure in accordance with FDA's proposed standards, FDA estimated the documentation burden to be approximately 0.5 hours or the mid-point between a reported range of 10 minutes to 48 minutes for process validation records. An additional two hours may be required initially to research scientifically valid information supporting the growers' soil treatment requirements and relevant application practices that may be applicable to the manure treatment, or to research alternative composting methods or alternative application intervals. While the cumulative impact of the cost burdens associated with the rule may cause a shift in management decisions, FDA does not anticipate that the nominal costs of recordkeeping for BSAs of animal origin to be excessive or overly burdensome such that it would result in a shift to chemical

[3] The reference for Evaluation of Recordkeeping Costs for Food Manufacturers is found within FDA's PRIA (FDA, 2013b), reference no. 16. See Docket No. FDA-2011-N-0921.

fertilizers. As reported in the PRIA (FDA, 2013b) the total cost burden per farm for recordkeeping under subpart F is anticipated to be $71.40 annually and an additional one time burden of $142.80 per farm.

With respect to handling and storage, FDA assessed in Chapter 4.3 the potential impacts associated with increased storage and transportation of untreated manure for the purposes of treating it for use. However, details such as material costs for new structures, the amount of manure needed for treatment (which drives other costs), and specific transportation costs are highly dependent upon the size and geographical location of the farm, among other factors. The likelihood of such a structure will be influenced by any minimum application interval ultimately established by FDA. As previously noted, FDA indicated in the 2014 supplemental notice that it will defer its decision on an appropriate minimum application interval until it pursues certain actions, including a robust research agenda, risk assessment, and efforts to support compost infrastructure development, in concert with USDA and other stakeholders.

FDA made no changes to the EIS based upon this comment.

Provisions to Control Wildlife

Comment: Several comments contended that FDA misinterprets the effect of proposed § 112.84 and, throughout the Draft EIS, mistakenly assumes that the language "does not authorize or require" has the same effect as "prohibits." The comments asserted that FDA wrongfully concluded that proposed § 112.84 will prevent farmers from impacting endangered species and that FDA must consider the impacts to endangered species that may arise from farmers taking measures to exclude animals.

One comment asserted that the Produce Rule may result in farmers destroying wildlife and its habitat to avoid postponing harvests and asserted that FDA should consider the environmental impacts of that practice. The comment cited to a 2007 survey of California produce growers that found close to 90 percent of growers surveyed used some type of practice to exclude wildlife in response to "food safety expectations."

Another comment stated that, relying on § 112.84 of the PS PR, FDA largely ignores the possibility that farmers may clear conservation buffers from field borders or riparian areas and drainages that would attract roaming livestock. The comment asserted that, while § 112.84 would not require farmers to fence or clear cut, neither does it prohibit such actions, and FDA fails to explain why it is not reasonably foreseeable that some growers will choose to build new fences or use clear-cutting to exclude animals. The comment stated that clearing habitat/non-crop vegetation including weeds can negatively affect bees, monarch butterflies, and birds.

Still another commenter asserted that FDA should analyze the environmental impacts associated with an alternative under which FDA would include proactive provisions in the rule to guard against habitat destruction and encourage co-management, along with impacts associated with proposed § 112.84.

Response: FDA has consulted with the USFWS throughout the rulemaking and NEPA process in order to understand the potential impacts that may result from the PS PR standards for domesticated and wild animals. As stated in the Draft EIS, which we are affirming in this Final EIS, we have determined that activities a grower may take with respect to threatened or endangered species is not an effect of the PS PR, if the provisions related to domesticated and wild animals are finalized as proposed (see Draft EIS, Chapter 4.0). Moreover, the comments misconstrue proposed § 112.84. The language in that section that states "does not authorize or require" does not have the same meaning as "prohibits." There is, in fact, no need for the Produce Rule to "prohibit" violations of the ESA; the ESA already prohibits such acts.

With respect to the concerns about farmers destroying wildlife, generally, and its habitat similar to what was found in a 2007 survey of California produce growers, we think the concerns are misplaced. FDA is aware of the actions that occurred in 2007 (e.g., some farmers took steps to eliminate wildlife, vegetation, and waterbodies), which are documented in Lowell et al. (2010). Through extensive outreach, FDA is also aware that since 2007 there is an abundance of educational opportunities, co-management strategies, conservation tools, and technical assistance that are available to farms through consultation with the USDA NRCS, universities, and agricultural industry groups, many of which were created to prevent methods such as those that occurred in 2007 from being used again. The events of 2007 occurred in the absence of clear guidance. FDA, USDA, conservation groups, and others recognized these steps as having been excessive. Based on conversations with USDA we are aware that many of the buffer zones that were removed and other actions that were taken in 2007 have since been reinstated. USDA and others have taken steps to provide guidance or training aimed at preventing these steps from recurring. Therefore, we do not consider significant impacts to result from the PS PR, on a national or regional level, that would be similar to the activities described in the 2007 survey.

With respect to proactively promoting co-management, FDA has promoted co-management throughout the rulemaking and EIS process. As required by section 419(a)(3)(D) of the FFDCA (21 U.S.C. § 350h(a)(3)(D)), in developing produce safety standards and consistent with ensuring enforceable public health protection, FDA took into consideration conservation and environmental practice standards and policies established by federal natural resource conservation, wildlife conservation, and environmental agencies. In developing the PS PR, FDA consulted with USDA's National Organic Program and NRCS, USFWS, and the EPA to take into consideration conservation and environmental practice standards and policies established by those agencies. Furthermore, FDA has consulted with the USFWS throughout the rulemaking and NEPA processes in order to more accurately predict potential impacts that may result from the PS PR to wildlife. We continue to encourage the co-management of food safety, conservation, and environmental protection. We intend to work with stakeholders to address co-management of produce safety and the environment.

Lastly, as noted above, to the extent that activities such as the clearing of borders surrounding farm fields may result from a management decision to exclude animals, and potentially impact certain habitats, we did not ignore these issues as the comment asserts and did address them in Chapters 4.5, 4.6, and 4.7 of the EIS. Proposed § 112.84 would clarify that there are no provisions in the PS PR that would constitute an undertaking, funding, permitting, or authorizing of any action by FDA

that is likely to jeopardize the continued existence of listed species or destroy or adversely modify designated critical habitat. This provision is intended to encourage the co-management of food safety, conservation, and environmental protection. FDA recommends that growers of produce coordinate with their local USFWS office of any activity that could potentially affect listed species or critical habitat (79 Fed. Reg. 58434 at 58464). The addition of proposed § 112.84 should help alert growers of the potential need for such coordination.

FDA made no changes to the EIS based upon this comment.

Antibiotic Treatment of Livestock and Poultry

Comment: One comment asserted that livestock and poultry animals are treated with antibiotics and, therefore, could theoretically promote the spread of antibiotic-resistant bacteria (citing fate and transport studies related to "industrial animal production" and effects on human health). The comment also stated that while FDA predicted that only small, short-term increases in livestock-induced soil compaction, concentrated animal waste, and use of chemicals, and also in affiliated short-term adverse impacts predicted would result from the PS PR, runoff containing (medically important) antibiotic-resistant bacteria would be considered a significant adverse impact.

Response: The standards for treated and untreated BSAs of animal origin and the alternatives considered in the EIS all rely on minimum application intervals between BSA application and harvest and/or treatment of raw manure. They do not create exemptions from these requirements for animals that are treated with antibiotics to control bacteria in the animal or its excreta. Therefore, the treatment of animals on livestock operations with antibiotics would not change as a result of any proposed requirements in the PS PR, if finalized. Further, the minimum application intervals between BSA application and harvest are not expected to result in any changes to existing conditions with respect antibiotic residues in BSAs on a regional or national level. Therefore, FDA made no changes in response to this comment.

Conflicts or Hazards Associated with Animal Exclusion or Intrusion

Comment: One comment asserted that we did not satisfy our obligation to take a hard look under NEPA in assuming that farmers will purchase alternative food sources for livestock or use other land for grazing to mitigate the impacts of § 112.82(a). The comment asserted that FDA cannot rest its conclusions about the impacts of the Produce Rule on voluntary and speculative management decisions by farmers and states that FDA does not provide any data to substantiate the availability of these alternatives or to support the likelihood that farmers would adopt such alternatives as opposed to clearing field or drainage borders. Another commenter urged FDA to consider additional environmental and biodiversity impacts related to wildlife exclusion measures, and further cited the debate over the creation of a national Leafy Greens Marketing Agreement, including findings of a survey by the Resource Conservation District of Monterey County (RCD). Regarding wild animal intrusion, one comment noted that USDA administers a conservation program through NRCS called the Wildlife Habitat Incentive Program (WHIP), a voluntary

program for conservation-minded landowners who want to develop and improve wildlife habitat on agricultural land. The comment asserted that FDA's proposed requirements would restrict (wild and domesticated) animals on agricultural land and that such a requirement may be in conflict with this important agricultural program. The commenter requested that FDA provide information as to the perceived conflict between Subpart I and other conservation programs.

Response: FDA did not intend to assume that farmers would need to purchase alternative food sources for domestic animals. The most common grazing activities typically occur in dedicated pasture land; produce fields and livestock management are not typically compatible. We acknowledge that the following sentence from Chapter 4.5 in the Draft EIS may have resulted in some confusion: "FDA does not believe that these types of actions are needed because of the availability of alternative food sources available for purchase or other land that may be used for grazing." Therefore, this sentence in the Final EIS has been revised for clarity to read, "FDA does not believe that these types of actions are needed because the grazing typically occurs in dedicated pasture land, and grazing where covered produce is grown does not generally occur during the growing season."

With respect to the assertion that FDA cannot rest its conclusions about the impacts of the PS PR on voluntary management decision by farmers, we disagree. See *C.A.R.E. Now, Inc. v. FAA*, 844 F.2d 1569, 1575 (11th Cir. 1988) (finding an effective voluntary noise abatement program to be sufficient to mitigate adverse environmental impacts); (*Ctr. for Food Safety v. Vilsack*, 844 F. Supp. 2d 1006, 1022 (N.D. Cal 2012) (finding voluntary best practices to be sufficient mitigation measure). With respect to the assertion that FDA rests its conclusions on speculative management decisions, we similarly disagree. As noted previously in Appendix E and elsewhere in this EIS, FDA relied on information provided through extensive public outreach conducted through FSMA stakeholder engagement, scoping for the EIS, comments provided on the 2014 supplemental proposed rule, and through direct consultation with USDA when developing the potential management decisions that farmers may make when attempting to comply with the proposed rule, and the relative likelihood that each management decision would be chosen.

As noted in the 2013 proposed rule and the 2014 supplemental proposed rule, we encourage the co-management of food safety, conservation, and environmental protection. We also acknowledged that one set of examples of biodiversity and conservation practices that may enhance food safety is available from the RCD (see 78 Fed. Reg. 3504 at 3586 and 79 Fed. Reg. 58434 at 58464). In addition, we noted that we provide this information as a resource and do not intend for it to suggest that we require or endorse a single approach. The commenter did not provide a reference for the survey conducted by the RCD. We believe that they are referencing, *A Grower Survey: Reconciling Food Safety and Environmental Protection* (RCD, 2007). We have reviewed this document on a national Leafy Greens marketing agreement. We do not agree that the data are appropriate for use in an analysis of potential impacts at the regional or national level. The survey conducted had limited responses (181 of 600 farms surveyed responded), was conducted in one region of a single state, and was conducted prior to the creation of best management practices currently in use. It is not possible to determine from the study if the impacts were representative of actions likely to be taken throughout California, much less the entire country, due to the extremely limited geographic scale of the survey. With regard to the debate this comment referenced, it is unclear what "debate" this comment refers to. Farming practices

vary by state due to the patchwork of existing state laws and regulations, as well as due to difference in weather, geography, soil type and conditions, existing vegetation, habitat and wildlife, historic practices and other factors. Therefore, it is not appropriate to extrapolate from the practices of this particular county to the national scale. It is also recognized that in response to the destruction of wildlife and its habitat in 2007 in California that led to the survey, that there has been increased discussion on the national scale on the need for best management practices which are in wide-scale use throughout the country. Therefore, the results of the study cannot reasonably be considered to be an accurate representation of the actions that are likely to be taken at the current point in time. For these reasons, FDA made no changes to the EIS based upon the survey or debate.

Moreover, through proposed § 112.84, we are proposing to make it clear in the final rule that the produce safety standards in no way authorize produce growers to "take" species or habitat protected by the ESA.

Relative to the comment regarding varying risks, FDA determined based on its Draft Qualitative Assessment of Risk (as referenced in the EIS as FDA, 2013c) that the number and type of pathogens detected in animal feces varies with the animal species. All kinds of animals can carry diseases that can contaminate produce meant for human consumption. As it can be exceedingly difficult to distinguish between animal scat by species, it is not feasible at this time to set a food safety standard based on species-specific pathways of contamination.

FDA will continue its outreach to farmers and industry groups in the rule's implementation phase. FDA has developed and continues to develop produce safety standards consistent with ensuring enforceable public health protection. FDA took into consideration conservation and environmental practice standards and policies established by federal natural resource conservation, wildlife conservation, and environmental agencies. In developing the PS PR, FDA consulted with USDA's National Organic Program and NRCS, USFWS, and the EPA to take into consideration conservation and environmental practice standards and policies established by those agencies. With respect to the commenter's reference to WHIP, FDA did also consider this program when preparing the Draft EIS; however, WHIP was repealed by the Agricultural Act of 2014. The USDA NRCS indicates on its Web site that portions of the WHIP Statute were rolled into the Environmental Quality Incentives Program (EQIP).[4] FDA did not identify any conflicts with EQIP or similar programs.

Health and Safety

Comment: One commenter asserted that FDA misapplies the consideration of both beneficial and adverse effects in its assessment of public health impacts from the BSA standard. The commenter stated that FDA acknowledges that workers will face increased chemical exposure in application of chemical inputs but asserts that the Draft EIS weighs the impacts on these workers against the public health benefits of the rule. The commenter states that FDA must separately acknowledge

[4] Information from USDA NRCS on WHIP and EQIP may be found at the following site: http://www.nrcs.usda.gov/wps/portal/nrcs/main/national/programs/financial/whip/.

the risks posed to agricultural workers and propose activities the agency can undertake to mitigate these impacts.

A commenter expressed concern that the Draft EIS states there would be a net benefit to public health but did not acknowledge an adverse impact and discount for workplace hazards on farms. The commenter went on to request that FDA acknowledge impacts to farm worker health and propose measures to mitigate the impacts.

Response: The commenter inaccurately characterizes the Draft EIS in suggesting that FDA balances the potential impacts to agricultural workers against public health benefits. FDA assessed the human health risk to farmworkers throughout Chapter 4 of the EIS, and we have added additional text specifically in Chapter 4.1 (No Action Alternative) regarding research that EPA has done to examine the potential harmful effects on public health from contaminants in fertilizers. As FDA reexamined the Draft EIS, we did, however, find a clerical error at page 4-35 that incorrectly identified "no impacts" to human health as a result of secondary or worker exposure to pesticides. FDA has corrected this sentence in this Final EIS to state, "As long as pesticides and other chemicals are applied in accordance with their labeling requirements, which would be a reasonably foreseeable use, FDA would not expect a significant impact on human health as a result of secondary or worker exposure to pesticides. Similarly, ***we would not anticipate significant impacts*** on ***minority primary operators*** or ***minority farm workers***" (emphasis added). The revised text may be found in the Final EIS in Chapter 4.2, under the management decision subheading titled *Switching water source*, Environmental Justice.

We believe this correction (incorporated into the Final EIS) makes the sentence consistent with the remainder of the analysis in Chapter 4.

Furthermore, chemical treatments are regularly used on farms and elsewhere. FDA's proposed regulation would not result in a substantial change in the way that farmworkers work with chemicals. Farmworkers and all users of such chemical products are required by FIFRA to use these products in accordance with their approved labeling requirements. The usage requirements could include proper training and the use of protective gear. As explained in Chapter 4.6.1, it is not reasonably foreseeable that farmworkers will be exposed to significant hazards or that significant adverse impacts to human health would result as an effect of the produce rule.

Impact on Tribes: Ground-Disturbing Activity

Comment: A comment requested that in the event of ground-disturbing activity within Tribal lands, an Inadvertent Discovery Plan be attached to the permit application. The comment included suggested language to consider when drafting Inadvertent Discovery Plans. The suggested language for drafting Inadvertent Discovery Plans discussed the appropriate steps for the "project proponent" to take "[i]n the event any archaeological or historic materials are encountered during project activity."

Response: In the context of this particular comment, the PS PR does not explicitly require ground-disturbing activity. Rather, the PS PR, in general, would only apply if a person/entity decides to grow, harvest, pack, or hold covered produce. In the event that a farmer is covered by the PS PR, the only types of activities that could be considered ground-disturbing would be typical farm land activities conducted by farmers that are commonplace and already occurring on farm lands such as tilling, planting, or harvesting. Furthermore, any ground disturbance conducted by individuals and companies on tribal lands should continue to be handled on a case-by-case basis and take into consideration all applicable regulations. Should an activity by individuals or companies in compliance with the final rule (if implemented) occur in areas of concern to a Tribe, the matter should continue to be handled on a case-by-case basis through the permit application filed by the individual or company seeking permission with the appropriate local or state regulatory agency. FDA is taking no steps which would require that Tribal lands be disturbed in any manner. Application of the rule is dependent on the farm within Tribal lands choosing to grow covered produce in locations of their choosing.

FDA made no changes to the EIS based upon this comment.

Impact on Minority Groups

Comment: One commenter asserted that FDA ignores impacts to minority groups other than Native American tribes. The commenter asserted that FDA generalized the impacts from minority agricultural workers and applied them to minority groups as a whole through the following language: "[T]here are no impacts anticipated on human health as a result of secondary or worker exposure to pesticides. Therefore, there are also no anticipated significant impacts to minority groups."

Response: With respect to the commenter's identification of "no impacts anticipated on human health," and as addressed in a prior comment response, FDA reexamined the Draft EIS and found a clerical error at page 4-35 of the Draft EIS that incorrectly identified "no impacts" to human health as a result of secondary or worker exposure to pesticides. FDA has corrected this sentence to state, "As long as pesticides and other chemicals are applied in accordance with their labeling requirements, which would be a reasonably foreseeable use, FDA would not expect a significant impact on human health as a result of secondary or worker exposure to pesticides. Similarly, ***we would not anticipate significant impacts*** on ***minority primary operators*** or ***minority farm workers***"" (emphasis added). The revised text may be found in the Final EIS in Chapter 4.2, under the management decision subheading titled *Switching water source*, Environmental Justice.

We disagree with the assertion that we generalized impacts from minority agricultural workers and applied them to minority groups as a whole. With respect to impacts on minority agricultural workers, as discussed in Chapter 3.7.3, FDA used the most recent data on farmworker ethnicity as supplied by the USDA ERS. Based on this information, 92 percent of farmworkers are reported as

being white (race) and 45 percent are reported as being Hispanic (ethnicity).[5] Employment data from the U.S. Department of Labor from surveys conducted in 1997 and 1998 estimated demographic data in terms of non-white race and Hispanic ethnicity; however, only state-level data for California is reported along with limited regional data that includes Arizona and Texas within certain regional data (portions of Arizona and Texas fall within important produce growing regions). In addition, Table 3.7-15 in Chapter 3.7.3 reports information on the demographics of principal farm operators. Through our analysis, FDA also identified minority populations that may be affected in Alaska and Hawaii, which is based on the overall percentage of minority groups, and not specific minority groups that may be specifically impacted by the rule. FDA provides a detailed analysis of potential impacts to minority primary operators and minority farmworkers within Chapter 4.7 of the EIS, based on data presented in Chapter 3.7.3 of the EIS.

Please note that the Agricultural Worker Protection Standard, or WPS, was established to reduce the risk of pesticide poisoning and injury among agricultural workers including those that handle pesticides. As such, EPA establishes the Agricultural WPS under the authority of FIFRA (7 U.S.C. 136-136y) (see Chapter 3.8.2). When handling such products, manufacturer labeling requirements convey proper handling techniques including using recommended personal protective equipment (e.g., chemically resistant gloves to avoid exposures that may otherwise cause unreasonable health effects). When following prescribed handling procedures, the risk from chemical exposure would be low. In addition, when EPA determines that a pesticide product can be registered for use, the EPA "has concluded that the use of the pesticide product will not cause unreasonable adverse effects to humans or the environment when applied according to the label directions and restrictions" (EPA, 2014m). In light of the requirements under FIFRA including farmworker training and safety requirements under the WPS, manufacturer labeling requirements, and EPA's pesticide registration process, FDA considers the handling and disposing of such products in accordance with existing regulation and labeling requirements a reasonably foreseeable use, and that the use in accordance with such requirements would not result in significant impacts to human health.

Distinct from our analysis of minority agricultural workers, FDA did consider impacts to vulnerable populations, including minorities, in various places throughout the EIS. For example, in both Chapter 4.7 and 5.5, FDA addressed the concern over whether the PS PR would result in vulnerable populations having reduced access or availability to fresh produce.

Tribal Consultation

Comment: Several comments noted that the Draft EIS does not mention individual tribes specifically and suggested that the figures in the Draft EIS showing reservations in conjunction

[5] Regarding the way that farmworker percentages are reported, Spanish, Hispanic, and Latino farm operators and workers are reported in all races: "Spanish, Hispanic, or Latino origin. Operators of Spanish, Hispanic, or Latino origin are found in all of the racial groups listed in the census and were tabulated according to the race reported, as well as on tables pertaining only to this group." Hispanic and Latino populations identify themselves as one race, then are broken out a second time so as to not be double-counted, so while the reporting is the same, the Spanish, Latino, and Hispanic race is a subset of the other races (USDA ERS, 2014a).

with growing areas and areas of concentrated livestock production are misguided. The comments asserted that impacts to sovereign tribes would be more widespread than FDA acknowledges. Specifically, the comments alleged that the rule would affect tribes with regard to land use and land management, groundwater draw down, and water rights, as well as treaty rights and the numerous tribes' trust relationship with the Federal Government.

Some comments stated that grouping tribal populations with other minority populations diminishes tribes' recognition as self-governing nations. One comment stated that the environmental justice analysis must take into account the unique political status of tribes, including tribes' land tenure status and litigated water rights relationships that are different from general minority property owners.

Additional comments state that tribal consultation on the Draft EIS was insufficient and inadequate, and that participation on a webinar or call does not constitute official individual government-to-government interaction with tribal leadership or duly authorized representatives.

Response: Due to the scope of the EIS and the number of federally recognized tribes, individual tribes were not listed. The FDA has engaged tribes in government-to-government consultation and other outreach through a variety of face-to-face meetings, webinars, and correspondence and will continue to do so throughout the FSMA implementation process.

The purpose of the map illustrations in the Draft EIS, Figure 3.7-6, is to show regional variations and impacts on a large scale at the state, regional or national level. It is not intended to provide specific impacts to specific tribes. In addition, FDA relied on information regarding tribes from USDA NASS to the extent that survey information was available for farms on tribal land and farms that are operated by Native Americans, whether or not they are located on Native American reservations. This information is addressed specifically in Chapter 3.7.3. It should be noted that agricultural information on Native American Tribes and on tribal land is not well reported.

Consultation, correspondence and discussions with tribes to date on the Draft EIS indicate that the two key issues for tribes are tribal sovereignty and water rights. Individual tribes have also raised issues regarding groundwater drawdown, land use and management, water rights and treaty rights. Tribal consultation on the FSMA rules is an ongoing process and will be continued as part of the FSMA implementation process.

FDA's consultation with Native American Tribes, as well as other outreach, has been ongoing throughout the process of preparing the Draft and Final EIS. Appendix D of this EIS outlines the consultation and other outreach that has taken place to date with federally recognized tribes.

As a result of these comments, we have removed the following statement from Chapter 3.7 of the EIS: "The majority of the environmental issues would affect a tribal entity the same as it would affect any minority property owner."

Impact to Disadvantaged and Vulnerable Populations

Comment: One comment indicated that the provisions of the PS PR would impose new and substantial administrative, financial, and operational burdens on farmers resulting in "theoretical environmental impacts," including direct impacts to land and indirect socioeconomic and human health impacts associated with reduced access to fresh produce and a lack of new employment for farmworkers that have lost their source of employment as a result of implementing the PS PR.

Another comment stated that FDA did not consider impacts to vulnerable populations, including minorities that would result from reduced access to fresh produce. The commenter asserted that a potential decline in the number of farms—either through the closing of small farms or the lack of entry of new farmers into the market—could result in decreased access to fresh produce or an increase in costs of fresh produce for consumers. The comment stated that any such increase in prices would be particularly hard on small, rural, and underserved communities, and that FDA's lack of evaluation of such potential impacts fails to satisfy the requirements of NEPA.

Response: FDA acknowledged in the Draft EIS, and reaffirms in this Final EIS, that there are many potential management decisions, including the decision to cease farming, that could result from implementation of a final rule. The EIS addresses this issue primarily in Chapters 4.2 and 4.7. There are many pressures that affect farmers and that influence the management decisions that a farmer may make at any given time (see Chapter 1.9 of the EIS).

With respect to potential impacts to land, FDA considered "Land Use" within the EIS in Chapter 4.0. FDA has determined that it would be highly speculative to assume how many businesses may lose their ability to operate, and where, as a result of a management decision to cease growing produce, and therefore, that it would be equally speculative to address impacts related to the inability to operate, including impacts on workers. Regardless of the speculative nature of any such impacts, we do not expect such impacts to be significant because the proposed rule, if finalized, would establish a series of exemptions or modified requirements where certain small entities would be either excluded from coverage based on average monetary value of produce sold (proposed § 112.4), or would be eligible for a qualified exemption based on average monetary value of food sold and direct sales to qualified end users (proposed § 112.5). These exemptions, as well as other management decisions available to the farmer, e.g., switching to a non-covered crop or changing irrigation methods, provide farmers that are most likely to be economically impacted by the rule with significant flexibility to avoid the loss of their land which would precede a land use change. For these reasons FDA does not anticipate any land use impacts.

FDA does not believe that finalizing the proposed rule would limit the availability or access of fresh produce to disadvantaged populations. FDA acknowledges in the EIS (see Chapter 4.7 and 5.5) that increases in farm operating costs may result in adverse impacts to farmworkers, but such costs may also be transferred to consumers by means of higher prices. Although potential cost impacts could be felt by consumers, any price increase may be indistinguishable from other present and ongoing pressures on produce farmers that also result in commodity price increases, e.g., drought, pests, and disease, which occur in different produce growing regions (see Chapter 1.9). The commenter is incorrect that we assessed such impacts only under subpart F. Our analysis is

presented also within Chapter 4.7 as a cumulative effect of the rule, and within Chapter 5.5 with no specific emphasis on any one subpart of the rule. We did, however, make some edits to Chapter 1.9 to add clarity to our thinking on potential produce price increases that may result from the rule.

With respect to indirect socioeconomic impacts, please refer to Chapter 3.7.3 Environmental Justice and Chapter 4.7.

Impact to Elderly Populations

Comment: One commenter indicated that the rule would induce adverse effects on the elderly portion of the farm population as well as the general populace.

Response: The analysis of the EIS considers the geographic and environmental conditions that are shared by all primary farm operators, as well as examines the management decisions that are available to all primary farm operators. Therefore, the potential environmental impacts associated with the rule are inclusive of the elderly portion of the farm population. Regarding the general populace, the EIS further examines environmental impacts that are shared among the general population including the effects of groundwater drawdown. However, FDA also acknowledges that, as a result of the rule, produce commodity prices may increase, although any price increase may be indistinguishable from other present and ongoing pressures on produce farmers that also result in commodity price increases, e.g., drought, pests, and disease, which occur in different produce growing regions (see Chapter 1.9).

FDA made no changes to the EIS based upon this comment.

Assessment of Management Decision to Cease Production

Comment: Some comments questioned the number of farms that may make a management decision to stop production of a covered crop and shift to non-covered produce, and questioned FDA's conclusion regarding domestically grown produce that, if some farmers ceased production as a result of the rule, lost production of covered produce would be replaced with imports. Some comments asserted that switching the type of produce grown may not be a realistic option for many farms with small acreage or who have niche markets, and that an increase in imported produce has potential impacts not considered, such as an increase in fuel use for shipping and an increase in safety risks to consumers. Comments stated that many provisions of this rule will impose new and substantial administrative, financial, and operational burdens on farmers, and that more analysis is needed for a management decision by farms to exit farming altogether and, for those who do shift crops, to alternative crops that may be chosen that could require more water or result in more soil erosion. Comments state that, with regard to what FDA asserts to be a lack of data relating to this issue, when specific data is unavailable, NEPA requires FDA to use theoretical approaches or research methods generally accepted in the scientific community to estimate these impacts, including direct impacts to land and indirect socioeconomic and human health impacts (if, for

example, certain at-risk populations have reduced access to fresh produce and certain farmers cannot find new employment).

Response: The comments provided no basis on which FDA could rely to revise its estimates of the number of farms that may decide to stop production or shift production to non-covered produce. We recognize that such options may not be viable for some farms, but assessing the number of farms that may have acreage that would not sustain a switch to non-covered produce or that may have a niche market would require data and information about individual farms at a local level, which is not consistent with the scope of the EIS we explained in Chapter 1.9.

We disagree with the characterization from these comments that FDA concluded that if some farmers were to cease production as a result of the rule, any decrease in production of covered produce would likely result in an increase in imports. While we conclude in this EIS that reduced production by certain farmers would likely be replaced by other farmers—either regionally, locally, or internationally—we have not made a determination that an increase in imports is likely as a result of the implementation of any final rule. Even if such an increase in imports were to occur, with regard to the comment's assertion that an increase in imports would result in an increase in safety risks to consumers, we disagree. Production abroad does not provide a means by which to avoid compliance with the final rule; therefore, there is no basis with which to assume any increase risk to consumer safety will result.

FDA made no changes to the EIS based upon this comment.

Cumulative Impacts

Comment: One comment asserted that the cumulative impacts assessment in the Draft EIS is insufficient because it does not consider the impacts of the Produce Rule in conjunction with the impacts of other FSMA rules. The comment argued that in assessing cumulative impacts, FDA must conduct a more extensive review of each of the FSMA rules than noting that each of the rules has been categorically excluded from the NEPA process.

Response: FDA has not changed its thinking on the applicability of the categorical exclusions cited within Chapter 5.3.1 of the EIS.

We continue to believe that there are no significant cumulative impacts when the FSMA rules are taken together. For example, as described in the supplemental notice, we proposed to revise the definition of "farm" such that a farm would no longer be required to register as a food facility merely because it packs or holds raw agricultural commodities grown on another farm under a different ownership. We are proposing that such activities would be subject to the produce safety rule rather than the Preventive Controls for Human Food rule. Chapter 5.4 has been edited to clarify other distinctions that exist between the PC HF PR and the PS PR, which include but are not limited to a much higher threshold for total annual sales for very small farms under the PC HF PR; the lack of standards for agricultural water, BSAs of animal origin, or domesticated and wild animals in growing areas; and that requirements for hand washing, cleaning and sanitization of

machinery and equipment, and recordkeeping would be duplicative of requirements under the PS PR, if finalized. Chapter 5.4 also discusses under what limited conditions a farm would be subject to both rules.

Other rules such as Third Party Accreditation, Foreign Suppliers Verification Programs for Importers of Food for Humans and Animals, and the Intentional Adulteration Proposed Rule have no overlap in terms of environmental impacts with the PS PR.

Collective Environmental Impacts

Comment: Several comments stated that FDA did not consider the cumulative impacts of actions that individually were not significant by not evaluating the water, soil, ecological and biological resources, air and human health impacts of the entire final rule. One comment provided an example where there is no analysis of impacts to soils from increased use of chemicals due to agricultural water and BSAs requirements, or from animal confinement combined with nutrient run-off and pesticide use. The comment asserted that FDA did not consider the collective environmental impacts from agricultural water, BSAs, and wild and domestic animal requirements. Another comment stated that the anticipated increases in soil compaction, concentrated animal waste, and chemical use beyond existing management practices could have direct adverse impacts on water, soils, and ecological resources despite their temporal reality.

Concluding that FDA did not consider collective environmental impacts from the PS PR's requirements, some comments expressed concern that we segmented or manipulated the scope of our actions in order to avoid findings of significance. In particular, one comment asserted that FDA impermissibly segmented the evaluation of various provisions of the PS PR. The comment stated that FDA considers the impacts to water, soil, biological and ecological resources, and air separately in the Draft EIS for each of the individual subparts at issue—standards directed to agricultural water (subpart E), standards directed to biological soil amendments of animal origin (subpart F), and standards directed to domesticated and wild animals (subpart I)—but asserts that FDA's effort to unify its segmented analyses at the end of Chapter 4 of the Draft EIS does not provide an assessment of the collective impact all the various provisions of the Produce Rule have on each individual resource. The comment asserted that this segmented structure leads FDA to underestimate the rule's complete environmental impacts on water, soil, biological and ecological resources, and air quality. With regard to water, the comment asserted that FDA does not take a hard look at the impacts to water that could result from the combination of increased pesticide use, animal confinement or other exclusionary measures, and decreased water availability. With regard to soil, the comment asserted that FDA does not consider the aggregate impacts on soils from subparts E and F of the Produce Rule and that we instead only consider the impacts to soils from subpart F; the comment further asserted that FDA needs to consider the combined impact of increased soil compaction, nutrient run-off, chemical fertilizers, and pesticides. With regard to biological and ecological resources, the comment requested that FDA consider the aggregate impacts that could result from increased chemical use, land clearing, hunting and trapping, peat mining, and nutrient runoff caused by the Produce Rule, which could cause a degradation of ecosystems or wildlife diversity. With regard to air quality, the comment asserted that FDA did

not consider the possibility that small, localized increases in air emissions from each subpart could, in the aggregate, lead to significant impacts as a result of local, regional, or national increases in GHGs, particulate matter, and ozone precursor emissions.

Response: We disagree that we did not consider collective environmental impacts from the PS PR's requirements. In conducting our analysis, we assessed impacts both by potentially significant provision (e.g., subparts E, F, and I), and combined for all provisions, including those that are potentially significant and those excluded from further analysis in Chapter 2.2, based on a farm's average annual value of either produce or food sold during the previous three-year period. Specifically, Chapter 4.7 includes impacts related to the combined or cumulative effects of each proposed standard assessed together. A cumulative assessment of these impacts follows Tables 4-4 through 4-6. Contrary to the commenters' assertions, we did not segment or manipulate the scope of proposed actions or related alternatives when determining the significance of corresponding impacts.

There are current and on-going significant impacts associated with water quality and availability and related impacts such as land subsidence, and the costs associated with locating and maintaining access to water. These conditions are documented in Chapter 3.1. The EIS in Chapter 5 acknowledges that actions taken by farmers to further draw down water resources would exacerbate these existing conditions. However, we agree that the cumulative impact analysis of the rule in Chapter 4.7 of the Draft EIS could more fully explore potential cumulative impacts to soils. Chapter 4.7 of the Final EIS has been revised to reflect the updated impacts analysis to consider the aggregate impacts to soils from all potentially significant provisions of the rule. For example, actions that result in an increase in reliance on groundwater would potentially also result in irreversible impacts to soils, particularly in regions B, C, D, I, J, and U, as well as the northeastern and northcentral reaches of Mexico that share an aquifer with regions D, I, or J; and irreversible impacts such as soil compaction may have corresponding impacts on the soil's ability to filter nutrients, chemical, and pathogens, which may also be impacted by a switch from BSAs of animal origin to chemical fertilizers.

The combined impacts for biological and ecological resources do not elevate the potential impacts to a significant level. Chapter 3.5.3 discusses how the impacts on air quality and GHGs were addressed primarily using a qualitative assessment on a national scale, but that a regional approach was also taken because covered farms and associated livestock operations are heavily concentrated in certain areas. As shown in the Impact Thresholds table (see Table 4-2), an impact to air quality and GHGs was considered significant if increases in criteria pollutant emissions would be likely to contribute to violations of the NAAQS standards and/or increases in GHG emissions would occur that could not be adequately mitigated using existing practices. We agree that there is the potential for emissions of air pollutants and GHGs that may result from a variety of aspects of the PS PR, and that these emissions will largely be regionally and/or locally concentrated. However, we do not consider these impacts to be significant at the scale analyzed due to the anticipated small relative increases in emissions of these gases, and we find that such impacts will not likely cause or contribute to increases in GHG emissions that may result in considerable short- or long-term public health concerns.

Chapter 5 assesses the cumulative impact of all the provisions of the PS PR together with a range of other past, present, and reasonably foreseeable future actions including related FSMA actions, comparable federal and non-federal actions (e.g., FDA Guidance to Industry, USDA Organic Regulations, Industry Marketing Agreements), and other non-specific actions that may result in a cumulative effect based upon the nationwide importance of the proposed rule (including oil and gas exploration, residential and commercial development, and groundwater drawdown in general).

Timeframe Evaluated in Draft EIS

Comment: One comment asserted that the Draft EIS does not include a meaningful cumulative impacts analysis because it limits "reasonably foreseeable future" impacts to those impacts arising within the six-year period following promulgation of the PS PR. The comment stated that FDA does not explain why the reasonably foreseeable future impacts of the PS PR, if finalized, should be limited to this six-year window. The comment stated that since the timeframe selected by FDA represents the date by which all farms must come into compliance with the produce safety rule's requirements, and since the produce rule's impacts will extend far into the future, FDA must consider impacts on a longer timeframe in its cumulative impact analysis.

Response: The Draft EIS erroneously indicated that the cumulative impacts analysis considered the six-year initial implementation period following enactment of a final rule. However, the analysis conducted in Chapters 4 and 5 actually considers impacts related to full implementation and does not indicate partial implementation was considered. As such, the introduction under Chapter 5.2 has been updated to clarify the time period subject to evaluation.

Connected Actions

Comment: One comment suggested that the Draft EIS failed to fully consider the potential environmental effects of the Produce Rule in conjunction with the PC HF PR because FDA does not consider the PC HF PR to be a connected action under NEPA. The comment asserted that the produce rule and the PC HF PR are interdependent, that both implement the Food Safety Modernization Act, and that, therefore, FDA cannot adequately assess the full impact of the produce safety rule without also analyzing the effects of the PC HF PR in the final EIS. The comment referenced the definition of connected actions (other than unconnected single actions) in 40 CFR 1508.25(a) and *Theodore Roosevelt Conservation P'ship v. Salazar*, 616 F.3d 497 (D.C. Cir. 2010) for support.

Response: The comment is incorrect in its assertion that we failed to fully consider the potential environmental effects of the PC HF PR (now a final rule, or the PC HF FR), as it relates to the PS PR, in the Draft EIS. As we stated in section 5.4 of the Draft EIS, the PC HF PR would require, and the since-finalized rule does require, registered food processing facilities, with some exceptions, to complete a hazard analysis and apply preventative controls. The agency prepared a categorical exclusion for that action. Some very small processing businesses (proposed $1 million in total annual sales of human food) would be excluded from the PC HF rule but may be required

to comply with the proposed requirements of the PS PR, to the extent such businesses conduct activities that are covered activities under the PS PR. These businesses were included as a farm subject to the PS PR in the Draft EIS. Further, there are many parts of the PC HF FR that would be similar to the PS PR (e.g., hand washing, cleaning, and sanitization of machinery or equipment, and recordkeeping). These parts are duplicative, and the environmental impacts of the related proposed requirements were considered as part of the Draft EIS.

Certain farms that would be subject to the PS PR and that also conduct additional processing or manufacturing may also be subject to the PC HF FR for those additional processing and manufacturing operations. These mixed-type facilities have sales of $1 million annually of all foods processed. However, the potential environmental impact from compliance with the PC HF FR, for which we determined a categorical exclusion was appropriate, would not result in a change to FDA's environmental impact analysis for these large farms. Further, the potential environmental impacts are already captured for these farms in the PS PR, and no additional environmental impacts are anticipated from compliance with any other requirement of the PC HF FR. The PC HF activities are all of the type that "does not individually or cumulatively have a significant effect on the human environment" (21 CFR 25.30(j)).

Whether or not one considers the possible overlap in requirements for these large farms, or requirements for any farms subject to the PS PR or the PC HF FR, as connected actions, FDA has considered the impact from farms that may be subject to requirements in both the PC HF PR and the PS PR in the Draft EIS (see Chapter 5 of the EIS). In any case, the fact that the preventive controls and produce safety statutory provisions were both enacted as part of the FDA Food Safety Modernization Act does not necessarily mean, in the NEPA context, that the implementing regulations are "connected actions." Connected actions are those actions that (1) automatically trigger other actions which may require environmental impact statements, (2) cannot or will not proceed unless other actions are taken previously or simultaneously, or (3) are interdependent parts of a larger action and depend on the larger action for their justification. 40 CFR 1508.25(a)(1). We do not consider the PC HF and PS rules to be "inextricably intertwined," for example, where each rule cannot proceed without the other and where the PC HF PR would not be finalized without the PS PR being finalized. *See Thomas v. Peterson,* 753 F.2d 754, 758) (9th Cir. 1985). In fact, as noted above, FDA finalized the PC HF rule without having finalized the produce safety rule. Even so, we have adequately considered the environmental impacts from the PS PR, alone and in relation to the PC HF rule, in the Draft EIS.

The comment cited The *Theodore Roosevelt Conservation P'ship v. Salazar*, 616 F.3d 497, 514 (D.C. Cir. 2010) in support of the need for consideration of the PC HF PR in the Draft EIS as a connected action. That case concerns the need for a comprehensive impact statement in situations where proposals for related actions that "will have cumulative or synergistic environmental impact upon a region are pending concurrently before an agency." That case is inapposite to the Draft EIS because the PC HF rule does not have cumulative or synergistic environmental impacts, when combined with those of the PS PR.

FDA made no changes to the EIS based upon this comment.

FDA's Analysis of Management Decisions

Comment: One comment expressed concern about the sufficiency of FDA's reference to potential management decisions as a means to mitigate the cumulative impacts of the Produce Rule with regard to water, soil, and biological and ecological resources. With regard to water, the comment stated that NEPA requires FDA to consider the impacts that may arise if farmers choose to chemically treat water, choose not to participate in voluntary marketing programs, or choose not to adopt certain nutrient management practices. With regard to soil, the comment questioned FDA's assumption that farmers will switch to the use of green manuring, no-till practice, and the use of covered crops as a form of mitigation, and asserted that FDA provides no data to supports its assumption that farmers will adopt such practices. With regard to biological and ecological resources, the comment asserted that NEPA requires FDA to consider the impacts that would arise if farmers select management decisions other than participation in voluntary marketing programs that will limit adverse environmental impacts and if farmers choose to take measures to destroy animal habitat or clear farm borders.

Response: It appears that some confusion arose resulting from the way the word mitigate was used in the Draft EIS. We have removed the term "mitigate" and "mitigation" in this Final EIS when used in the context of evaluating the environmental impacts from management decisions farmers may take in response to the PS PR to avoid confusion with mitigation steps the agency may take to reduce the environmental impact of an action. We do discuss mitigation measures in response to environmental impacts assessed, as appropriate. FDA has added a section to Chapter 4.7 to address mitigation measures in a more centralized manner.

With regard to the specific impacts that the comments asserted FDA did not consider sufficiently, we disagree. The comment provided no specific information that leads us to question our conclusions that the potential management decisions noted in the comment will help limit cumulative impacts of the rule with regard to water, soil, and biological and ecological resources.

Potential impacts that may arise if farmers were to choose to chemically treat water, for example, appears in Chapter 4.2. The impacts analysis of Chapter 4 assumes impacts in the absence of participation in a marketing agreement or complying with the state-mandated nutrient management plans. However, to the extent that farms to participate in marketing agreements and do comply with the requirements of nutrient management plans (as mandated by 45 states nationwide), FDA assesses in Chapter 4 that potential environmental impacts resulting from the rule may be somewhat minimized. For those that participate in marketing agreements, which encompasses a high percentage of the produce growers in the U.S., whether participation is voluntary or mandatory, the requirements of the marketing agreements are mandatory for those who participate and are in many ways comparable to or sometimes more stringent than what is proposed in the PS PR. Similarly, the nutrient management plans place state-mandated requirements for farmers on their activities that are important for reducing impacts to water quality and soils, such as how best to apply and store manure or chemical fertilizers. As described in Chapter 4.2, FDA, in consultation with USDA and through the public involvement process, identified a series of reasonable management decisions that farmers may consider when faced with complying with the

requirements of a final rule. These management decisions along with options for the minimization of impacts to water are found throughout Chapter 4. In addition, FDA offered Appendix B on a variety of irrigation methods. We acknowledge that there are many other choices for irrigation that the EIS does not explore. These methods are highly dependent upon a variety of factors, such as water availability, affordability, crop, and meteorological climatic conditions, which vary across the country and even by region. FDA did assess the impacts associated with switching water sources in Chapter 4.2.1 under Alternative I. While FDA does not believe that under Alternative I switching water sources would be a preferred management decision, the EIS acknowledges that it is still a possibility under the alternative and that significant impacts from water withdrawals are already occurring and that any management decision under this alternative to further withdraw irrigation water as needed would exacerbate the current conditions and would result in significant impacts. FDA provided throughout Chapter 4 several reasonable management decisions to address the most likely scenarios that a farmer may make when faced with implementing a final rule. The management decisions, and farmer's likely decisions were developed through the public involvement process and through consultation with USDA. FDA has no stated preferences for any management decisions. For example, FDA received numerous public and industry comments submitted on the supplemental proposed rule (79 Fed. Reg. 58434) that microbial die-off (including a post-harvest rinse) or other similar mechanism is a viable and reasonable management decision, which may reduce the use of chemicals to treat water used for irrigation.

Information supporting our conclusion that farmers will likely adopt practices such as green manuring, no-till practice, and the use of covered crops appears in Chapters 4.1, 4.3, 4.4, and 4.7. The use of green manuring and other no-till practices are current trends, as identified in Chapter 3.3.3.6 and 3.4.3.1, for which we believe will continue based upon the data and literature we reviewed. We disagree with the suggestion that we overemphasize the use of green manuring and cover crop practices when determining the significance of impacts. The analysis looked at other factors such as the very small amount of farms nationwide (2.3 percent) using untreated BSAs of animal origin and the adherence to nutrient management plans (required by 45 states nationwide) when assessing these impacts and properly put them into scale.

Information supporting our conclusion regarding the limited impacts that might result to biological and ecological resources as a result of participation in voluntary marketing programs appears in Chapters 4.2, 4.3, 4.4, and 4.7.

Information supporting our conclusion that no significant environmental impacts would result from any measures taken to destroy animal habitat or clear farm borders appears in Chapters 4.5, 4.6, and 4.7. The PS PR, if finalized, does not require a farmer to take measures to destroy animal habitat or clear farm borders in order to meet the requirements of the proposed food safety standards. We note that before taking any action to destroy habitat or clear farm borders, landowner's are responsible for consulting with the appropriate regulatory agencies and to receive permits, if required, such as if wetlands or waterways are present on or directly adjacent to the property and may be impacted by the actions a farmer may take, or if there is the potential for threatened and endangered species (or critical habitat) to be present on the property. The proposed rule does not remove the farmer's responsibility to follow federal, state, and local conservation laws. FDA clarified in the preamble to the supplemental proposed rule that growers of produce

should also be aware that clearing or manipulation of habitats, including activities affecting water resources, groundwater or natural vegetative cover, can affect species listed as threatened and endangered. The supplemental proposed rule further stated that growers can identify whether any listed species may be present in their area by checking USFWS's Endangered Species Web site and Information, Planning, and Conservation System website; that growers should coordinate with their local USFWS office on any activity that could potentially affect listed species or critical habitat; and that growers could contact their local USFWS office for any additional information.

Mitigation Measures Relating to Standards Directed to Agricultural Water

Comment: One comment asserted that FDA incorrectly assumed in the Draft EIS, in three key ways, that farmers will take voluntary measures to mitigate the impacts of the standards directed to agricultural water. First, the comment asserted that FDA erred in asserting that the impacts of the increased use of chemicals to treat water would be "mitigated by the ability of covered farmers to choose other management decisions," including "switching water sources, switching the irrigation method to a non-contact method, or adding mechanisms to account for microbial die-off in the field and post-harvest." The comment stated that FDA provided no support for its assumption that farmers will always choose one of these alternative management decisions or that these alternative decisions would mitigate the impacts from increased chemical treatment. Second, the comment asserted that FDA incorrectly relied on noncontact irrigation and other voluntary measures by growers in assessing environmental impacts, to the exclusion of a discussion of the environmental impacts associated with subpart E if farmers do not switch irrigation methods. The comment stated that the switching of irrigation method is an option for only a limited variety of crops. Third, the comment asserted that FDA failed to explain why it is not reasonably foreseeable that some farmers will still choose to chemically treat water or switch water source to meet the proposed agricultural water standards, rather than waiting the appropriate amount of time for the die-off rate. The comment stated that, while the flexibility of the proposed standards may decrease the number of farms that either use chemical treatment or decide to switch water source, FDA goes too far in its conclusion that microbial die-off will "overall mitigate the potential need for or significant impacts associated with other management decisions." The comment asserts that in times of drought, farmers may not have the luxury of being able to wait the appropriate amount of time for the die-off rate.

Response: FDA recognizes that there are many potential management decisions that might result from implementing a final rule. There are many pressures that affect farmers and that influence the management decisions that a farmer may make at any given time (see Chapter 1.9). FDA, in coordination with USDA, identified the reasonably foreseeable actions, i.e., management decisions, that businesses potentially affected by any final rule might take in order to come into compliance with, or to potentially avoid being subject to, the alternatives under consideration for inclusion in the final rule. Moreover, in response to the PS PR, FDA received some comments from industry detailing the steps that would be needed to be in compliance with the rule. FDA considered for analysis those management decisions that were expressly stated or implied in those comments. Therefore, through consultation and public involvement FDA anticipates that farms would use one or a combination of the management decisions we identify in the EIS depending

upon their individual conditions. Based on these comments and discussions, we identify a number of management decisions for each of the alternatives, and do not limit the analysis solely to one decision. The analysis considers the potential environmental impacts of the management decisions identified for each alternative.

Management Decisions Pertaining to BSA Provisions

Comment: One comment asserted that FDA overemphasized that farmers will always adopt certain management decisions and, in so doing, failed to take a hard look at the impacts of the BSA provisions. Relating to the implementation of longer application intervals under Alternatives I, III, IV, and V, the comment asserted that FDA improperly relied on the presumption that best management practices will be used by farmers in determining that the longer manure storage times and potential increase in manure runoff—and the related impacts to surface water, groundwater, and soils—would be significantly mitigated by farmers' implementation of voluntary management practices. Additionally, relating to the use of chemical fertilizers, the comment asserted that FDA partly relies on the assertion that there is a "growing trend away from chemical fertilizers to practices such as green manuring" in concluding that the restrictions on the use of BSAs of animal origin and potential switch to chemical fertilizers will not have significant environmental impacts. The comment stated that it is unreasonable for FDA to rely so heavily on a trend that is both voluntary and wholly outside of the agency's control. The comment also disagreed with FDA's assumption regarding the pervasiveness of green manuring and cover crop practices and noted that while a few farmers on the cutting edge of the soil health initiative are growing the kind of high biomass, multispecies cover crops and using the kind of minimum-till minimum-chemical methods needed to protect soil health, most vegetable producers need BSAs to maintain soil quality. The comment asserted that in some parts of the country, practices like green manuring are used on approximately 2 percent of total acreage and that, while that figure is likely to be higher among produce growers, it is very unlikely to be above 30 to 40 percent, and may be considerably less. The comment stated that vegetable production is a very intensive system, and both the soil and the farmer are often too occupied for effective cover cropping.

Another comment stated that FDA did not consider reasonably foreseeable management decisions relating to treated BSAs. The comment asserted that FDA considered only potential management decisions relating to the proposed waiting period and stated that the provisions relating to treated BSAs also require certain procedures regarding the use, handling, and storage of BSAs, as well as record-keeping requirements.

Response: We disagree with the assertion that this EIS concludes that farmers will always adopt certain management decisions. We also disagree with the assertion that we failed to take a hard look at the impacts of the BSA provisions. No management decision is expected to be absolute. Individual farmers across the nation are expected to select their preferred management decision based on their own unique conditions. The variability of these decisions by farmers within a region will likely limit the overall impacts of the rule because there would not be one type of impact expected within a region that could result in a more concentrated environmental impact to one resource area (e.g., water or soil). In consultation with USDA and through the public involvement

process, FDA does not believe that ceasing to grow covered produce or going out of business are likely management decisions that farms may make for treated BSAs when considering the administrative procedures for handling treated BSAs of animal origin.

Regarding potential impacts from the PS PR's untreated BSA standard, FDA proposed to establish no specific minimum application interval in proposed § 112.56(a)(1)(i) and is proposing to defer its decision on an appropriate minimum application interval until it pursues certain actions, including a robust research agenda, risk assessment, and efforts to support compost infrastructure development, in concert with USDA and other stakeholders. As such, we will continue to assess potential industry impacts, and explore mitigation measures that may help alleviate potential negative consequences associated with this standard.

With regard to use of green manuring, as previously stated in Appendix E, the information supporting our conclusion that farmers will likely adopt practices such as green manuring appears in Chapters 4.1, 4.3, 4.4, and 4.7. The use of green manuring and other no-till practices are current trends, as identified in Chapter 3.3.3.6 and 3.4.3.1, for which we believe will continue based upon the data and literature we reviewed (Magdoff and van Es, 2009). We disagree with the suggestion that we overemphasize the use of green manuring and cover crop practices when determining the significance of impacts. The analysis looked at other factors such as the very small amount of farms nationwide (2.3 percent) using untreated BSAs of animal origin and the adherence to nutrient management plans (required by 45 states nationwide) when assessing these impacts and properly put them into scale.

FDA made no changes to the EIS based upon this comment.

FDA's Discussion of Mitigation Measures

Comment: One comment asserted that FDA's analysis of mitigation alternatives is insufficient in that it relies solely on mitigation activities that can be undertaken by farmers, rather than actions of FDA itself, and that, because FDA does not control or otherwise incentivize certain actions of farmers, these actions are speculative at best. The comment cites to *Ohio Valley Envtl. Coal. v. Aracoma Coal Co.*, 556 F.3d 177 (4th Cir. 2009) in support of the assertion that NEPA prohibits agencies from relying upon speculative mitigation measure and asserts that FDA's focus on farmer management decisions impermissibly shifts the agency's burden to mitigate impacts to affected farmers. The comment states that FDA must provide a reasoned discussion, supported by analytical data, of mitigation measures within its control.

Response: It appears that some of the basis for confusion arose from the way the word mitigate was used in the Draft EIS. FDA has revised the EIS to correct this issue.

With regard to the assertion that our analysis of mitigation alternatives is insufficient, we disagree. NEPA does not "create a general substantive duty on federal agencies to mitigate adverse environmental effects." CEQ, Final Guidance for Federal Departments and Agencies on the

Appropriate Use of Mitigation and Monitoring and Clarifying the Appropriate Use of Mitigated Findings of No Significant Impact (76 Fed. Reg. 3843, 3846; Jan. 21, 2011). While CEQ regulations require that federal agencies discuss, as part of an EIS, possible mitigation measures in defining the scope of the EIS, 40 CFR 1508.25(b), the Supreme Court has recognized "a fundamental distinction . . . between a requirement that mitigation be discussed in sufficient detail to ensure that environmental consequences have been fairly evaluated, on the one hand, and a substantive requirement that a complete mitigation plan be actually formulated and adopted, on the other." *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 352-353 (U.S. 1989) (holding that NEPA required neither that "action be taken to mitigate the adverse effects of major federal actions" nor that NEPA imposed a "substantive requirement . . . to include in every EIS 'a detailed explanation of specific measures which will be employed to mitigate the adverse impacts of a proposed action'"). While an EIS must explain in detail "any adverse environmental effects which cannot be avoided should the proposal be implemented," 42 U.S.C. § 4332(2)(C)(ii), "NEPA 'does not require agencies to discuss any particular mitigation plans that they might put in place,' nor does it 'require agencies -- or third parties -- to effect any.'" *Theodore Roosevelt Conservation P'ship v. Salazar*, 616 F.3d 497, 503 (D.C. Cir. 2010) (*quoting Citizens Against Burlington, Inc. v. Busey*, 938 F.2d 190, 206 (D.C. Cir. 1991).

Applicability of Other Agencies' Resources

Comment: One comment contended that we did not satisfy our obligations under NEPA by relying on the expenditure of another agency's resources to mitigate the environmental impacts of the Produce Rule.

Response: We are not relying on another agency's mitigation of environmental impacts to satisfy our independent NEPA obligations. The comment does not identify the agency resources or the mitigation of impacts to which it refers. To the extent the comment suggests that FDA must mitigate environmental impacts of the PS PR, if finalized, we disagree. While NEPA requires us to discuss possible mitigation measures, NEPA does not require us to effectuate a mitigation plan or discuss future mitigation plans (*see Theodore Roosevelt Conservation P'ship v. Salazar*, 616 F.3d 497, 503 (D.C. Cir. 2010). We discussed possible management decisions available to farmers of covered produce throughout the EIS, evaluated the environmental impacts of those decisions on a regional and national scale, and also discussed measures that may reduce the potential environmental impacts from the PS PR, if finalized, consistent with our NEPA obligations. Therefore, we are making no changes in response to this comment.

Applicability of Clean Water Act Requirements

Comment: One comment suggested that we placed too much reliance on the Clean Water Act to mitigate impacts from chemical runoff, unintended release of stored manure, and moving livestock to new land. The comment stated the CWA is not applicable to most farming activities and that the National Pollution Discharge and Elimination System (NPDES) permitting system only applies to concentrated animal feeding operations (CAFOs) in agriculture. Furthermore, the comment

asserted that FDA underestimated environmental impacts to water resources; biological and ecological resources; soil; and waste generation, disposal, and resource use by presuming that compliance with the Clean Water Act (CWA) and complimentary state nutrient management plans will limit impacts. The comment based this assertion on three points.

First, the comment asserted that the Draft EIS overestimated the number of farms that are required to obtain National Pollutant Discharge Elimination System (NPDES) discharge permits under the CWA and that most agricultural operations are specifically exempted from needing these permits to operate. The comment stated that only when a farm is operating a concentrated animal feeding operation is that farm required to apply for an NPDES permit, and that even then, many farmers are able to simply avoid the permitting process. The comment stated that CWA regulations also make explicit exceptions for ongoing farming operations and irrigation activities for the dredge and fill permit program.

Second, the comment asserted that the Draft EIS erred in assuming that, if a farm has a NPDES permit or dredge and fill permit (and, perhaps, even if it does not), adherence to permit requirements will prevent any significant environmental impact. The comment asserted that FDA fundamentally misunderstands the nature of CWA permitting programs and stated that NPDES permits and dredge and fill permits allow activities to be conducted that will impact water resources. The comment asserted that FDA cannot rely on permits that fundamentally allow for pollution as a means to mitigate environmental harm.

Third, the comment stated that for those farms that are not obligated to apply for an NPDES permit, FDA incorrectly assumed that compliance with state nutrient management plans will also mitigate the Produce Rule's environmental impact, as shown by the fact that agricultural runoff is the leading cause of pollution in our waterways in spite of the CWA or the implementation of state nutrient management plans.

Response: We are not relying on the Clean Water Act in our evaluation of impacts from chemical runoff, unintended release of stored manure, and moving livestock to new land in a manner that is not consistent with our NEPA obligations. We recognize that the number of farms that may require such permitting may be limited. For example, we do not rely on the fact that some covered farms are required to obtain a NPDES permit as a means to satisfy our NEPA obligations related to chemical runoff. The final EIS does not rely on the issuance of permits under the CWA to be sufficient to find no significant impact from farms that use or manage untreated manure. Rather, we identify that adverse environmental impacts from the use or management of untreated manure could occur in no more than 2.3 percent of farms affected by the rule nationwide. Further, we do include discussion, where applicable, about what compliance with NDPES permitting requirements would mean in helping to minimize environmental impacts on a regional or national level, consistent with our need to consider possible mitigation measures (*Theodore Roosevelt Conservation P'ship v. Salazar*, 616 F.3d 497, 503 (D.C. Cir. 2010) (stating that NEPA does require an agency to discuss possible mitigation measures (citations omitted)), *Ctr. for Food Safety v. Vilsack*, 844 F. Supp. 2d 1006, 1023 (N.D. Cal 2012) (holding that USDA Animal and Plant Health Inspection Service (APHIS) adequately considered the effectiveness of mitigation measures that consisted of best management practices, joint agreements, and contractual

agreements for which APHIS had no oversight authority). Further, we do appropriately evaluate voluntary or mandatory programs, such as nutrient management plans, as a means to mitigate potential environmental impacts (*C.A.R.E. Now, Inc. v. FAA*, 844 F.2d 1569, 1575 (11th Cir. 1988) (finding an effective voluntary noise abatement program to be sufficient to mitigate adverse environmental impacts); (*Ctr. for Food Safety v. Vilsak*, 460 F.3d at 1022 (finding voluntary best practices to be sufficient mitigation measure). Considering the small amount of farms that would be affected by the rule (approximately 2.3 percent of farms, or roughly 820 nationwide) and the effectiveness of the plans that are in place already within most states throughout the U.S., the assessment of less-than-significant impacts is reasonable. Further, the concern the comment raises about certain activities, such as dredge and fill operations, that the comment states would be exempt from CWA regulations is moot since we are not relying on the fact that a farm has a NPDES permit to support an outcome on the significance of an impact.

Compliance with Another Agency's Requirements

Comment: One comment asserted that, by presuming compliance with another agency's requirements, FDA "impermissibly abdicates its NEPA obligations." The comment cited to *Calvert Cliffs' Coordinating Comm., Inc. v. Atomic Energy Comm'n*, 449 F.2d 1109, 1122-23 (D.C. Cir. 1971) and *Southern Oregon Citizens Against Toxic Sprays, Inc. v. Clark*, 720 F.2d 1475, 1480 (9th Cir.1983) for support. Another comment suggested that reliance on the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) does not account for extra-label or misuse of pesticides and does not reduce risks to zero from their use. The comment asserted that FDA underestimated the potential environmental impacts by assuming that compliance with FIFRA will limit impacts to water resources, biological and ecological resources, and human health. The comment asserted that because FIFRA does not establish a permitting system for pesticide use and instead regulates solely through registration and labeling, risks associated with the release of pesticides in a particular geographic location at a particular time are not even evaluated. The comment stated that agricultural chemical runoff is a serious cause of environmental harm to water resources as well as biological and ecological resources that depend upon water and that, under NEPA, FDA cannot rely solely on an assertion that pesticides are regulated under FIFRA in taking the requisite hard look. The comment also stated that FDA did not conduct the necessary hard look under NEPA by assuming that no environmental impact will be caused by the chemical treatment of water because EPA may someday approve a label for the chemical treatment of agricultural water under FIFRA. The comment stated that FDA relied upon this hypothetical approval to protect the water from harm. The comment asserted that FDA cannot assume that speculative future actions of EPA will entirely mitigate these impacts.

Response: Regarding the comment that asserts we abdicated our NEPA obligations by presuming compliance with another agency's requirements, it is not clear what other agency requirements the comment considered. To the extent these comments suggest that we are relying on the fact that a pesticide chemical is registered under FIFRA as a means to satisfy our NEPA obligations, we disagree. The *Calvert Cliffs'* and *Southern Oregon* cases cited in support of the comment stand for that narrow proposition and are inapposite to our analysis. Further we disagree with other comments that we underestimated the potential environmental impacts by assuming that

compliance with FIFRA will limit impacts to water resources, biological and ecological resources, and human health. We did not simply rely on an assertion that pesticides are regulated under FIFRA as a means to support our determination that there are no significant impacts to water, biological and ecological resources or human health from the use of pesticides.
The comments seem to be confusing our evaluation of environmental impacts with our discussion of possible mitigation measures that may reduce the environmental impact. Our reference to, and evaluation of, another agency's regulatory and environmental review in this EIS concerning a pesticide use is consistent with our need to consider possible mitigation measures (*Theodore Roosevelt Conservation P'ship v. Salazar*, 616 F.3d 497, 503 (D.C. Cir. 2010) (stating that NEPA does require an agency to discuss possible mitigation measures (citations omitted)), *Ctr. for Food Safety v. Vilsack*, 844 F. Supp. 2d 1006, 1023 (N.D. Cal 2012) (holding that USDA Animal and Plant Health Inspection Service (APHIS) adequately considered the effectiveness of mitigation measures that consisted of best management practices, joint agreements, and contractual agreements for which APHIS had no oversight authority). In response to these comments, we are making changes, as appropriate, to our descriptions of the potential environmental impacts from a pesticide that may be approved in the future for use for the antimicrobial treatment of agricultural water used during the growing of crops to avoid confusion with how we consider mitigation measures in relation to our evaluation of environmental impacts.

There is no EPA-registered pesticide that is approved for use for antimicrobial treatment of agricultural water used during the growing of crops (note proposed § 112.44(c) pertains to agricultural water that is applied in a direct water application method used during the growing of produce (other than sprouts)). We have generally referred to this use of water as "irrigation water" in this document.). In the water quality discussion (Draft EIS, pg. 4-22), we stated that EPA-registered pesticide products are evaluated to determine potential environmental effects and potential impacts to human health specific to their use. We said further that FDA does not have specific information on the pesticides that would be submitted to EPA for registration for uses to control pathogens in irrigation water applied to produce prior to harvest (id). If we had a lawful use of an EPA-registered pesticide for irrigation water, we would consider the analysis and findings of EPA with respect to an evaluation of the environmental impacts resulting from a reasonably foreseeable use of that water on covered produce. We did discuss in the Draft EIS oversight by EPA should someone submit an application for a pesticide use with irrigation water, but we are not able to conclude what the environmental impacts may be for a use that is currently unknown and simply speculative. Moreover, we evaluate the environmental impacts from pesticide use to treat water used for post-harvest treatment in Chapter 4.2.

For the same reasons, we do not rely on an EPA review of a registered pesticide to treat agricultural water to assess environmental impacts to other resources that depend upon water, such as biological and ecological resources, on a regional or national level. FDA cannot predict what the future actions of EPA will be with respect to registration of a pesticide to treat agricultural water, much less evaluate the impacts that using unknown pesticides to treat agricultural water would subsequently have on other resources. We do discuss, and consider it appropriate to discuss, EPA oversight and how that may minimize adverse impacts for chemicals that in the future may be registered for use in agricultural water. Moreover, we do generally evaluate the potential

environmental impacts from agricultural water treated with pesticides on biological and ecological resources in Chapter 4.2.

We did consider the general types of limitations and restrictions EPA provides in pesticide labeling for the use and handling of pesticides by workers on farms as part of our discussion of mitigation measures when considering pesticide use by workers generally. To the extent there are specific pesticide uses registered by EPA in the future for treatment of agricultural water, FDA would evaluate in future rulemaking related to such treatment the significance of environmental impacts as required by NEPA from such use (see *San Francisco Baykeeper v. United States Army Corps of Eng'rs,* 219 F. Supp. 2d 1001, 1013 (N.D. Cal 2002) (finding the Corps' decision-making process was adequate and that it fulfilled its statutory and regulatory duty of independent evaluation under NEPA where the Corps included a concise summary of the Port's EIR with respect to invasive species, cited and attached the documents on which it relied, and issued a FONSI explicitly "based on a review of information incorporated in the" EA). We acknowledged in Chapter 4.2 that there is the possible risk of chemical exposure to site workers that may have to handle the chemicals prior to application to agricultural water, but these risks are minimized when using proper handling techniques including using recommended personal protective equipment in accordance with labeling requirements or product recommendations (e.g., chemically resistant gloves to avoid exposures that may otherwise cause unreasonable health effects) as described by the manufacturer. Chapter 4.1 also addresses the mandates placed on growers to ensure the protection of their workers from exposures to hazards including chemical hazards (e.g., the Worker Protection Standard).

With respect to comments about extra-label or misuse of pesticides, such uses are not reasonably foreseeable. In evaluating the potential environmental impacts that might arise if an agency were to take a specific action, NEPA permits an agency to make predictions of future activities under the assumption that people will make rational choices. *See, e.g., North Crawfish Frog v. Federal Highway Administration*, 858 F. Supp. 1503, 1523 (D. Kan. 1994) (upholding as reasonable under NEPA a decision by the Federal Highway Administration to finalize an environmental impact statement that presumed that drivers would make rational choices in calculating the most expedient route). Our conclusion that farmers will act in a manner consistent with FIFRA, and in a manner that will avoid wasting expensive pesticides and exposing workers to potential dangerous substances beyond the levels that have been deemed safe, is based on a conclusion that farmers will act reasonably. We acknowledge in Chapter 4.2 that there is the possible risk of chemical exposure to site workers that may have to handle the chemicals prior to application to agricultural water. We consider such risks to be speculative at this point because there is no registered pesticide for such a use. We discuss mitigation measures from proper handling techniques described by the manufacturer and the use of recommended personal protective equipment in accordance with product labeling (e.g., chemically resistant gloves to avoid exposures that may otherwise cause unreasonable health effects). Chapter 4.1 also addresses the mandates placed on growers to ensure the protection of their workers from exposures to hazards including chemical hazards (e.g., the Worker Protection Standard). The comment provided no data or information regarding the misuse of pesticides by produce farmers.

With respect to the comment that pesticide use does not reduce the risks to zero, we agree. However, in evaluating potential environmental impacts under NEPA, "[t]he government does not need to show that there is no risk of injury, but only that the risk is not significant." *Anderson v. Evans*, 350 F.3d 815, 832 (9th Cir. 2003); *see also Mid-Tex Electric Cooperative, Inc. v. Federal Energy Regulatory Com.*, 773 F.2d 327, 340 (D.C. Cir. 1985). We do not say that there would be no impacts if pesticides are used; rather, we concluded in the Draft EIS, and reaffirm in this Final EIS, that such impacts from pesticides would not be significant.

Comment: One comment suggested that the Draft EIS dismissed concerns related to increasing confinement of animals that would likely result from the implementation of requirements on animal grazing in produce fields and contact with agricultural water by deferring to EPA oversight under the Clean Water Act. The comment cautioned about reliance on EPA's oversight under the Clean Water Act because of reports that no accurate inventory of animal confinement operations is available.

Response: FDA does not agree that we dismissed concerns related to increasing confinement of animals that would likely result from the implementation of requirements on animal grazing in produce fields and contact with agricultural water by deferring to EPA oversight under the Clean Water Act. While we did consider EPA's role in requiring permits for certain facilities (i.e., CAFOs) that store raw manure and may perform composting operations (see Chapter 3.4.2 Regulatory Oversight), we did this in conjunction with an analysis of the potential impacts related to the rule and taking into account the existing impacts that such permits have on background conditions. The EIS also considered nutrient management plans, which are a strategy to support the Clean Water Act, and are required for farmers to comply with in 45 states, in the same context. Existing laws, regulations and programs are key to understanding the background conditions, as well as in helping to determine the contribution the results of certain management decisions may have to potential impacts, as these requirements for farmers include not only how fertilizers (untreated and treated) are applied, but also how they are stored to ensure farmers are in compliance with state and federal regulations. Nutrient management plans are addressed in Chapters 3.3.3.6, 3.4, and 3.5. Compliance with state nutrient management plans, which may minimizes potential environmental impacts associated with the rule, are addressed in Chapters 4.1, 4.3, 4.4, 4.5, and 4.7. FDA further estimated as a basis of analysis that nationwide there are only 2,829 dual- and multi-purpose farming operations that raise livestock or poultry and also raise produce (estimated 8 percent of affected farms, assuming that, at most, all 2,829 dual- and multi-purpose farms are affected by the rule) (see Chapter 2.1 subpart F, including Table 2.1-3 and 2.1-4). Chapter 4.5 in the Draft EIS further states that there are few of these operations that exist that may be subject to the rule, and the that relative impacts are not significant because fencing and other animal exclusion measures are likely already in place. Moreover, the data on the number of farms potentially impacted (USDA NASS, 2014a) and the information from EPA is the best available data FDA has on such operations in order to assess potential impacts.

Threatened and Endangered Species: References to Endangered Species Act

Comment: One comment stated that FDA failed to consider impacts to endangered species and relied upon the Endangered Species Act to underestimate impacts. The comment stated that NEPA does not permit FDA to avoid consideration of impacts to threatened or endangered species by assuming the U.S. Fish and Wildlife Service (USFWS) will protect endangered species under the ESA.

Response: The FDA did not rely on the ESA to underestimate impacts under NEPA and did consider whether there are effects that must be considered under NEPA from the PS PR. As we explained in the Draft EIS, to the extent that growers would take any actions that may impact a threatened or endangered species, such activities would be subject to the independent oversight and authority of the United States Fish and Wildlife Service and would not be an activity caused by the proposed requirements related to animal intrusion in proposed § 112.83. Consequently, the proposed requirements in § 112.83 would not be the legally relevant "cause" of the effect under NEPA, and any impacts would not be an "effect" within the meaning of 40 CFR 1508.8 that FDA would need to analyze in the EIS. *See Dep't of Transp. v. Pub. Citizen*, 541 U.S. 752, 770 (2004) (stating "We hold that where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered a legally relevant 'cause' of the effect."). Therefore, we are making no changes to the EIS in response to this comment.

Management Decisions with Respect to Domesticated Animal Provision

Comment: One comment asserted that FDA made certain presumptions about which management decisions farmers will choose and, in so doing, failed to take a hard look at the impacts of the domesticated animal provision. The comment stated that FDA ignored potential management decisions, such as the likelihood that farms with integrated crop-livestock systems would stop raising livestock and would stop growing covered produce, which decision would reduce the diversity of the farming operation and result in attendant environmental impacts and impacts to public health and communities.

Response: The Draft EIS addressed, and this Final EIS continues to address, impacts due to fencing and other actions that a farmer could take to exclude domestic livestock. In Chapter 4.5, FDA assessed that it is highly likely in the case of the dual- and multi-purpose farms (estimated at 2,829 farms assumed to both grow covered produce and raise livestock) that in most cases fencing already exists as a means to managing livestock. The most common grazing activities would occur in dedicated pasture land where perennial grasses grow. Produce fields and livestock management are not typically compatible because livestock, if allowed to graze in produce fields, would consume much of the commodity. FDA used the best available data from USDA and other sources to make this determination. FDA did not exclude the possibility that clear-cutting may be needed, but as discussed in Chapter 4.5, we conclude that such actions are expected to be temporary measures to allow fence construction in the few instances where construction may be needed. We

do not believe such cases would be prevalent to the extent that impacts from fencing would rise to a level of significant impacts at a regional or national level.

Adherence to USDA's NRCS

Comment: One comment asserted that FDA's reliance on USDA's Natural Resources Conservation Service (NRCS)'s conservation programs as a means of mitigation is misplaced and that such reliance leads FDA to underestimate impacts to water resources. The comment stated that participation in NRCS programs is voluntary and that any potential mitigation of environmental impacts is limited to those who choose to participate. The comment also stated that NRCS programs focus primarily on activities beyond food safety on produce farms and that individual NRCS offices simply may not have the resources or expertise to mitigate the specific environmental impacts caused by the Produce Rule. Another comment asserted that FDA shifted the burden of mitigating environmental impacts of the Produce Rule to farmers by assuming farmers will adopt technologies traditionally promoted through technical assistance of the NRCS, such as strip tillage, the use of green manure, and implementation of riparian buffers. The comment asserted that by shifting the burden to farmers, FDA "impermissibly abdicates its NEPA obligations."

Response: We disagree that our discussion in the Draft EIS of USDA's NRCS's conservation programs as a means of mitigation was misplaced. We acknowledged the fact in the Draft EIS that the NRCS Conservation Practice Standards (CPS) program is a voluntary program; however, many of these practices would serve as mitigation measures for potential impacts associated with implementation of the rule (*C.A.R.E. Now, Inc. v. FAA*, 844 F.2d 1569, 1575 (11th Cir. 1988) (finding an effective voluntary noise abatement program to be sufficient to mitigate adverse environmental impacts); (*Ctr. for Food Safety v. Vilsak*, 460 F.3d at 1022) (finding voluntary best practices to be sufficient mitigation measure). Notwithstanding our conclusion that our references to NRCS's conversation programs as a means of mitigation was misplaced, we have removed references in the Final EIS to the NRCS CPS program as a mitigation measure. Chapter 4.9 includes a revised discussion of mitigation.

Reliance on Marketing Agreements

Comment: Some comments expressed concern about a finding of limited impact based on adherence to marketing agreements or orders. The comments stated that such agreements and orders may not cover a large percentage of farms, and particularly small operations.

Response: We determined that while many of these marketing agreement programs are voluntary, the practices of these programs are often mandatory for those who choose to participate in the programs. A few programs, such as T-GAPs, are mandatory for growers of certain commodities. In addition, many marketing agreements have similar standards that are more stringent than what FDA proposes. Example programs and their particular requirements that are relevant to FDA's proposed standards (for potentially significant provisions) are found in Chapter 2.1 at Table 2.1-

1, and Chapter 5.3 at Table 5.3-1. FDA further determined that regions B, C, D, I, J, and U are regions in which more than 80 percent of covered produce is grown in the United States, and that a high percentage of the growers in these regions already participate in State or industry marketing agreements. We consider the information that we have, related to adherence to marketing agreements or orders, to be appropriate to include in our analysis of environmental impacts.

Marketing Agreements and Good Agricultural Practices

Comment: One comment asserted that FDA assumed incorrectly that the compliance of farmers with voluntary marketing programs or Good Agricultural Practices will limit environmental impacts to water resources and waste generation, disposal, and resource use. The comment stated that FDA concluded that impacts to water from the Produce Rule will be minimized because some voluntary marketing agreements maintain more restrictive standards than the Rule and that many farmers are already complying with the requirements that would be established by the proposed rule, if finalized. The comment asserted that this conclusion does not account for the fact that (1) some farmers have chosen not to opt into the programs, (2) some farmers grow produce not covered by these programs, and (3) some farmers may choose to opt out of these programs in the future.

Response: We disagree that compliance with voluntary marketing programs or Good Agricultural Practices would not have an impact on the significance of environmental impacts to water resources and waste generation, disposal and resource use when compared to those who do not so comply. More than 80 percent of covered produce is grown in regions in which a majority of growers participate in marketing agreements (some examples provided in Chapter 2.1 and 5.3). Many of these programs reduce impacts to water resources through various means, such as by regulating the application of untreated or treated manure, thereby reducing impacts related to agricultural run-off. Moreover, for those who participate in voluntary marketing agreements, certain requirements are more restrictive than those proposed in this rulemaking. For example, the California LGMA places a more restrictive standard on irrigation water quality than what FDA proposes under subpart E Alternative I (see Chapter 2.1, Table 2.1-1). Therefore, certain environmental impacts that may occur as a result of these more restrictive requirements are not impacts resulting from the rule, but are already occurring under a marketing agreement. So too, certain environmental impacts that may be lessened by adherence to the marketing agreements would be important for us to consider in our analysis of the environmental impact of these related provisions in our PS PR. We understand that not all farmers opt into these programs, do not grow produce covered by some of these programs, and may choose to opt out of a program. As we discussed in Chapter 1.9, the conditions in farming are not static and management decisions by an individual grower can change over time.

Good Agricultural Practices/Industry Standards and the Impact of BSA Provisions

Comment: One comment asserted that FDA implied in the Draft EIS that no environmental impacts will be caused by farmers switching to treated BSAs as long as they adhere to industry

standards or GAPs. The comment asserted that this is implied in Chapter 4.3 of the Draft EIS (Subpart F / Untreated BSAs of Animal Origin and Human Waste), under the potential management decision heading, *Switch to treated materials*, for the "Waste Generation, Disposal, and Resource Use" discussion component. The comment stated that industry standards and GAPs are voluntary and are not necessarily relevant to environmental health issues. The comment also contended that FDA entirely relied on industry standards or GAPs to mitigate impacts caused by the potential management decision of farmers switching to treated BSAs (or synthetic ones) in response to the PS PR.

Response: The comment mischaracterized what the Draft EIS assessed in terms of impacts related to the management decision for switching to treated material. The section of the Draft EIS to which the comment cites specifically relates to impacts associated with Waste Generation, Disposal, and Resource Use. This section of the Draft EIS states that most farms that would be covered by the rule are already using chemical fertilizers, treated (composted) material, or no-till practices such as green manuring, as opposed to using untreated material (raw manure). This section of the Draft EIS also states that, for those farms that presently use a composting method, not all composting operations follow a scientifically proved method for the elimination of pathogens such as what is prescribed by GAPs or industry guidelines. Therefore, as explained in the Draft EIS, switching to a treatment method that is scientifically proven may require the farmer to conduct more regular testing of the compost material in order to meet scientifically proven guidelines, but we do not anticipate any environmental impact from such testing. We note that other sections of Chapter 4.3 specifically related to switching to treated material do address potential environmental impacts. For example, the application of dried material with reduced moisture content from composting results in a potential risk of airborne and windblown material to impact the water quality of receiving water bodies. Such impacts are not considered significant because the amount of treated material that could be windblown is relatively small.

We disagree with the suggestion that the Draft EIS implied that no environmental impacts will be caused by farmers switching to treated BSAs as long as they adhere to industry standards or GAPs. Therefore, we are making no changes to the EIS in response to this comment.

State and County Permits to Limit Impacts to Wildlife

Comment: One comment asserted that FDA failed to satisfy its obligations under NEPA by relying on state and county permits for hunting, trapping, or poisoning of wildlife in assuming that such activities will not result in significant environmental impacts. The comment asserted that increased hunting, trapping, or poisoning of wildlife in response to the Produce Rule, even if legally permissible and regulated by states or counties, will negatively impact biological and ecological resources.

Response: We disagree with the comment's assertion that we relied on the fact that the issuance of a state or county permit for hunting, trapping, or poisoning of wildlife means there will be no significant environmental impacts. In the Draft EIS, we stated we were considering whether there are any potentially significant environmental impacts to wildlife, generally. In addition, we

recognized that there may be effective measures to minimize such impacts, such as government regulation and permitting. We considered the fact that proposed § 112.84 makes it clear that the PS PR would not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages (Chap. 4, pg. 4-74). We did not receive comment to the Draft EIS that hunting, trapping, or poisoning of wildlife would occur to any significant degree and are not aware of any information or data to indicate this is would occur in response to the PS PR, if finalized. Thus, we do not consider the PS PR, if finalized, would result in a significant environmental impact to wildlife on a regional or national level. In response to this comment, we include clarifying language in the final EIS to avoid confusion about our analysis of impacts in relation to a state or county permit for hunting, trapping, or poisoning of wildlife.

Definition of Significance: Chemical Water Treatment and Fertilizers

Comment: Two comments questioned FDA's conclusion that an increased use of chemical water treatments and fertilizers would be considered insignificant because effects may be reversible and not permanent. The comments asserted that, particularly when local factors are considered, the chemicals can leach into air and water and create acute health threats for local communities in the short-term. One comment asserted that this analysis ignored potential short-term, significant impacts associated with the increased use of chemical water treatments and improperly conflates the evaluation of beneficial and adverse impacts in concluding that there will be no significant impacts to agricultural worker health caused by increased exposure to chemicals used to treat agricultural water. Another comment asserted that FDA ignored potentially significant short-term soil health impacts as well as long-term impacts that degraded soil has on other biological and aquatic resources that could result from the increased use of chemical fertilizers. Other comments asserted that a required waiting period for harvesting after intrusion of domesticated animals could lead farmers to keep livestock in more concentrated enclosures, which could result in soil compaction with increased waste runoffs, including risks of spreading antibiotic resistance bacteria from antibiotic use with livestock.

Response: We acknowledge that some of the language in the Draft EIS incorrectly suggested that we had determined that impacts from chemical water treatment and fertilizer use would not be significant because the effects may be reversible. The Final EIS has been edited in Chapters 4.2 and 4.3 to clarify impacts related to the reversible nature of impacts to resources. As we stated in our response to the comment on "Compliance with Another Agency's Requirements," we are not aware of an EPA-registered pesticide that is approved for use for antimicrobial treatment of agricultural water used during the growing of crops and are not able to conclude what the environmental impacts may be for a use that is simply speculative. With regard to the use of chemical fertilizer, given the very small number of farms nationwide that could possibly consider a switch from untreated BSAs of animal origin to chemical fertilizers (approximately 821 farms nationwide, or 2.3 percent of all covered farms), we do not anticipate such impacts to be significant at a regional or national level.[6]

[6] Also note that 821 farms that would made a switch to chemical fertilizers represents approximately 0.04 percent of all 2,109,303 farms nationwide.

Definition of Significance: Standards Directed to Domesticated and Wild Animals

Comment: One comment asserted that FDA's evaluation of potential impacts relating to the standards directed to domesticated and wild animals failed to properly consider the potential significance of short-term or reversible impacts with respect to establishing a waiting period before harvesting after the intrusion of domesticated animals on crop areas or evidence of wild animal intrusion on crop areas. The comment asserted that FDA incorrectly concluded that the potential impacts associated with these provisions (i.e., soil compaction; more concentrated water runoff; increased use of herbicides, rodenticides, and other chemicals) would not constitute a significant environmental impact because they are short-term, and that FDA's analysis impermissibly ignored the potentially significant short-term impacts to water, soils, and biological and ecological resources that could result from these standards. The comment stated that FDA's determination that a relatively small amount of produce and farms are likely to be impacted by the provisions is insufficient to satisfy the requirement that FDA consider the regional and local impacts of these standards under NEPA.

One comment also noted that the Draft EIS stated that reduced grazing of domesticated animals in rotations including fields used for growing covered produce could occur and accordingly could increase animal confinement. The comment noted that the Draft EIS stated that increased concentrations and durations of animal confinement can lead to soil compaction (which can increase runoff) and more unconfined concentrated animal waste in runoff. Regarding wild animals, the comment stated that requiring farmers to wait an appropriate period to harvest after wild animal intrusion may increase the use of rodenticides and other chemical deterrents to exclude wildlife. The commenter disputed the idea that because FDA anticipates these issues to be short-term they are therefore not significant.

Response: We disagree with the commenter's suggestion that we failed to consider significant short-term impacts related to water, soils, and biological/ecological resources under the assessment for subpart I. We do, however, agree that some edits were required to our assessment under subpart I to more thoroughly clarify the relevance of the longevity or permanence of potential effects as they related to our significance factors presented at the beginning of Chapter 4.

With respect to domestic animal grazing, Chapter 4.5 states that domesticated animals, whether they are allowed to graze in covered fields, are removed from fields for an adequate or specified waiting period, or are fully excluded from fields growing covered produce, would be expected to result in localized soil compaction and thus, increased run-off of nutrients and contaminants into receiving waters, and contributing to (non-point source pollutants to) already poor water quality conditions. We do not believe such impacts to be significant because livestock management does not occur in produce fields, as livestock, if allowed to graze in produce fields, would consume much of the produce commodity. Therefore, grazing animals, e.g., bovines, that are large and may otherwise create some surface soil compaction, are by-and-large already excluded from produce fields and are likely to already be confined. Because these animals may be presently confined, the impacts to soils from compaction and to waterbodies from run-off are already occurring and so the current conditions would not be exacerbated as a result of the rule. We do not believe that on a

regional or national scale there are the number of circumstances that exist where excluding livestock (e.g., bovines) from a produce field in order to observe an adequate waiting period would raise impacts to a significant level. Such circumstances may represent a very small subset of the dual- and multipurpose farms that would be covered (in other words, a very small subset of 2,829 farms nationwide). We further believe any impacts related to soil compaction from grazing to be reversible because soil surfaces are more reactive to vegetation growth, moisture absorption, and weather processes, as opposed to deeper soils that are more susceptible to permanent compaction as influenced by groundwater pumping.

Fowl such as geese and chickens that are sometimes used to graze for insects or remove weeds in fields in lieu of using commercial pesticides do not pose a risk of soil compaction and any environmental impacts that are associated with soil compaction. Given that relatively few dual- or multipurpose farms use poultry as pest control in areas where covered crops are grown (estimated at the lower end of between 1.5 and 8 percent of all covered farms), any corresponding switch to using insecticide/pesticide would be very limited and is not anticipated to significantly contribute to degradation of water quality conditions nationwide.

We edited the beginning of Chapter 4 to more clearly identify how we defined and applied significance as it relates to the resource components evaluated in the EIS and to identify the conditions under which we consider the potential significance of management decisions and alternatives proposed in the EIS. Edits were made within Chapter 4.5 to clarify impacts related to any short-term or long-term anticipated effects, and to ensure consistency with our impact criteria by relaying those impacts that may be reversible.

With respect to wildlife intrusion, we do not expect impacts to soil compaction or concentrated water run-off because these impacts could not occur relevant to the management decisions assessed in Chapter 4.6, which include decisions to not harvest the field or to harvest part of the field, or to take measures to exclude wildlife. We believe our assessment of potential impacts related to chemical use (e.g., herbicides or rodenticides) to exclude animals is appropriate. Any potential land clearing that involves the application of chemicals to kill herbaceous species, or any type of rodenticide that may be applied adjacent to the farm field, if used in accordance with labeling requirements, would be anticipated to have minimal, but no significant adverse environmental impacts to water quality because the chemical compounds used to clear borders, for example, would not persist (e.g., are broken down by microbial activity, soil properties, photodegradation), and water quality would return to ambient conditions.

Definition of Significance: Compliance with FDA/CEQ Regulations

Comment: Some comments expressed concern about what the commenters viewed as FDA's adoption of a more limited definition of significance in the Draft EIS than what is required under NEPA. One comment asserted that FDA adopted an incorrect and limited test for "significant impacts," which resulted in FDA's lack of analysis of certain environmental impacts. The comment stated that while 40 C.F.R. § 1508.27 (adopted by FDA at 21 C.F.R. § 25.5(a)(19)) requires FDA to consider both the context of the action and the intensity of its effects in evaluating

significance, the Draft EIS used a more limited definition of "significant impacts": namely, those impacts that are "readily apparent; the overall impacts may be the result of a deliberate or essential shift in management practices, which may cause an overall substantial beneficial or adverse consequence." Another comment related to the scope of the EIS and the defined thresholds of significance. This comment stated that FDA's interpretation of significance is too narrow and fails to consider short-term, local, and individually insignificant effects that may have a cumulative impact. The comment suggested that this definition ignored certain impacts that should have been considered significant.

Response: With regard to the broader comments about FDA's use of the word "significant," FDA's NEPA regulations (Title 21 CFR part 25) are consistent with CEQ's NEPA implementing regulations (40 CFR parts 1500 through 1508). FDA appropriately analyzed the significance of the impacts in accordance with Title 21 CFR part 25. The commenter is correct in that FDA adopted CEQ's regulation at 21 CFR § 25.5(a)(19) for the term "significantly" (40 CFR 1508.27). Accordingly, in the beginning of Chapter 4, under the subheading, *Impact Definitions and Thresholds*, FDA explains how the terms "significant" and "not significant" impacts are applied to resource components and management decisions evaluated in the EIS. This Final EIS further clarifies the usage of these terms.

Due to the variety of potential impacts, FDA also established individual threshold levels for each resource component (See Table 4-2 in the EIS). The commenter is correct in stating that according to 40 CFR 1508.27, what is considered "significant" requires the consideration of both context and intensity. Table 4-2 of the EIS presents each resource individually to ensure that impact thresholds are thoroughly analyzed in terms of context and intensity. This Final EIS incorporates additional edits to Table 4-2 that provide further clarification relating to context and intensity.

We assessed potential short- and long-term impacts to the human environment throughout Chapter 4 of the Draft EIS, and we have made additional modifications within Chapter 4 of this Final EIS to clarify impacts related to any short-term or long-term anticipated effects, and to be consistent with our impact criteria by relaying those impacts that may be reversible. With respect to the assertion that this EIS fails to consider local impacts, we disagree that we are required to consider local impacts for purposes of this EIS. An updated explanation of the scope of this EIS appears in Chapter 1.9. While we acknowledge that 40 CFR 1508.27(a) provides that when considering context as a means of analyzing significance, significance varies with the setting of the proposed action and that, "in the case of a site-specific action, significance would usually depend upon the effects in the locale rather than in the world as a whole," our proposed rulemaking is not site-specific, as it potentially impacts more than 35,503 farms nationwide. As such, we have determined that a more reasonable approach to assess the significance of impacts in the context of this EIS would include a nationwide, regional, and, where possible, state-level assessment, based on the best information available.

Impacts of Administrative and Procedural Burdens

Comment: One comment asserted that the additional administrative and procedural burdens required by the rule could result in farmers electing to switch to chemical fertilizer, stop growing covered produce, or shut down the farm.

Response: The potential impacts associated with the administrative provisions of the produce rule are addressed in Chapter 2.2, and the impact analysis for subpart A within Chapter 4.7 takes into consideration the overall cost of implementing all provisions of the PS PR, if finalized. We have seen no specific information that leads us to question our conclusion expressed in the Draft EIS that these provisions will not result in significant environmental impacts. The comment provided no specific information in support of its assertion.

Commitment to Sustainability

Comment: One comment asserted that FDA did not consider an alternative set forth in the scoping and rulemaking comments requesting that FDA analyze the impacts of codifying language to promote co-management and actively guard against habitat destruction.

Another comment asserted that FDA did not take a hard look at the impacts of the standards in § 112.83(b) when it assumed that farmers will always adopt certain co-management measures and best management practices that allow farmers to direct wildlife away from fields while still providing adequate habitat. The comment stated that because these measures and practices are voluntary and fall outside of FDA's control, it is unreasonable and impermissibly speculative for FDA to rely upon them to mitigate impacts. The comment stated that FDA could have considered the impact of codifying language that would create incentives for farmers to preserve wildlife habitat, and that such language would have made it more reasonable for FDA to assume that farmers would use co-management to mitigate impacts, but to the extent that FDA relies on the assumption that farmers will voluntarily adopt certain co-management measures and best management practices, its discussion of environmental impact is inadequate.

Response: As required by section 419(a)(3)(D) of the FFDCA (21 U.S.C. § 350h(a)(3)(D)), in developing the proposed produce safety standards, FDA took into consideration conservation and environmental practice standards and policies established by federal natural resource conservation, wildlife conservation, and environmental agencies. Moreover, FDA has consulted with the USFWS throughout the rulemaking and NEPA process in order to more accurately predict potential impacts that may result from the PS PR, if finalized.

In addition, in developing the proposed requirements, FDA consulted with USDA's National Organic Program and NRCS, USFWS, and the EPA to take into consideration conservation and environmental practice standards and policies established by those agencies. FDA's proposed requirements encourage the application of practices that can enhance food safety, including sustainable conservation practices. Additionally, as discussed in Chapter 1 of the EIS, this

proposed rule is designed to be compatible with existing conservation practices in the management of agricultural water systems.

We did not assume "that farmers will always adopt certain co-management measures and best management practices that allow farmers to direct wildlife away from fields while still providing adequate habitat" as the comment asserts. We clarify in the Final EIS the impacts resulting from habitat destruction activities, e.g., herbaceous clearing around the borders of farm fields, as addressed in Chapters 4.1, 4.5, and 4.6. We continue to encourage the co-management of food safety, conservation, and environmental protection. We intend to work with stakeholders to address co-management of produce safety and the environment. Co-management by itself is not protective of food safety and therefore does not meet the purpose and need of the EIS; therefore, co-management on its own cannot be considered as a reasonable alternative. However, because co-management and other conservation practices are intrinsically considered in the proposed requirements, co-management and actively guiding against habitat destruction are in essence present as a component of all alternatives.

With respect to mitigation measures generally we added a section to Chapter 4.7 to address in a more centralized manner a discussion of mitigation measures. As explained elsewhere in Appendix E, however, the comment is incorrect in asserting that because certain measures and practices are voluntary and fall outside of FDA's control, it is unreasonable and impermissibly speculative for FDA to rely upon them to mitigate impacts. See *C.A.R.E. Now, Inc. v. FAA*, 844 F.2d 1569, 1575 (11th Cir. 1988) (finding an effective voluntary noise abatement program to be sufficient to mitigate adverse environmental impacts); (*Ctr. for Food Safety v. Vilsak*, 460 F.3d at 1022 (finding voluntary best practices to be sufficient mitigation measure).

Impact on Organic Growers

Comment: One comment stated that if FDA does not protect the right of organic growers to use practices that co-manage for conservation and food safety, it will be actively constraining growers from becoming certified organic and risk impairing the ability of existing organic growers to stay certified.

Response: Nothing in this rule will prevent organic growers from remaining certified under the USDA Certified Organic program. In developing the proposed requirements, FDA consulted with USDA's National Organic Program to take into consideration conservation and environmental practices and certification standards and policies. FDA's proposed requirements do not conflict with, or discourage compliance with, NOP requirements. FDA encourages the application of practices that enhance food safety and sustainable conservation practices. The comment provided no information in support of the assertion that the produce rule would hamper the certification process for organic growers.

Substantive Comments on the Draft EIS

Substantive comments that FDA received on the Draft EIS follow this page.

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Environmental Impact Statement (EIS) for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Comment On: FDA-2014-N-2244-0007
Draft Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Notice for Public Meeting on Draft Environmental Impact Statement

Document: FDA-2014-N-2244-DRAFT-0373
Comment from Andrew Aguilar, NA

Submitter Information

Name: Andrew Aguilar
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General Comment

Understandably, foodborne illness is a large issue and improvements in growing, harvesting, packing, and holding of produce, will be steps in the right direction. However, as a consumer, my initial concerns are towards the effect on price of vegetables and fresh fruits resulting from the rules proposed. It's perceivable that the cost of compliance for small farmers would likely result in increased cost of production across the board. The issue of the cost of compliance for those small time farmers, in my opinion, requires more thought beyond the provised increased time of compliance. Likewise, no reference or mention of sustainability was made in the provisions, yet certainly is an important factor to consider in regards to longevity. Lastly, in terms of standards of agriculture water no there was no specific guideline for frequency of testing. I'm curious to know whether it has been increased/decreased from the USDA's Good Agricultural Practices stipulations of three times a year.

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Environmental Impact Statement (EIS) for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Comment On: FDA-2014-N-2244-0007
Draft Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Notice for Public Meeting on Draft Environmental Impact Statement

Document: FDA-2014-N-2244-DRAFT-0356
Comment from Amanda Anderson, NA

Submitter Information

Name: Amanda Anderson
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Organization: NA

General Comment

My concern is regarding the new preventative controls rule and the produce standards rule. I fear that these new rules will make it impossible for local farms to continue to stay in business. These are the people that I trust to give us safe and local food. Many of the terrible stories we hear about from food contamination come from factory farm systems - not the local farms. I am a firm believer of the One Size Does Not Fit All model. We cannot treat local farmers the same as factory farmers. If we do, it will literally be impossible to get natural food sources in America. These small farmers will not be able to afford the new modernization changes. I know that I do not want to live in a country where I cannot purchase what I consider safe foods.I have a list of concerns I would like to comment on and will do so now.

First of all, the definition of a farm is at debate. The FDA wants to define it as an establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (or seafood), or both. This sounds find. But the only farms that are exempt from the rule are those that:

Pack or hold raw agricultural products;

Manufacture or process food for on-farm consumption only;
Dry/dehydrate raw agricultural products, as long as there is no additional processing; and/or
Label and package raw agricultural products as long as there is no additional processing.
To me this is saying that ALL farms who sell at farmers markets or CSAs will be mandated to follow these new rules. This will put all local and organic farmers out of business. The food market will be an oligarchy, with all safe food options non-existent.

Another concern of mine is the manure and compost regulations. Using chemicals instead of natural methods is not always better. In fact, it is often more harmful. We are making farming way more difficult and costly than it actually needs to be. Not only that, but it is less effective. Using chemicals, many of which are known carcinogens, to make our soil more healthy is not, in fact, doing what it says it is. It may work for a while, and it may look pretty, but the reality is that it causes cancer. It causes sickness in the plant, soil, animal, and person. There is absolutely nothing wrong with using manure and compost as a way to put nutrients back into the soil.

Conservation practices are also being changed. Farmers will be responsible for making sure that no animals are able to touch the food. At this rate all our foods will come from indoors using fake uv lights rather than the sun. Natural conservation practices, however, work just as well, and are also cost friendly. For one thing, the natural habitat can be useful. There are beneficial insects that can kill pests, raptors that can serve as rodent control, and other animals that can put a stop the need of the use of toxic chemicals. Other things, like stream-side vegetation, wetlands, grassed filter strips, windbreaks, and hedgerows are some of many options to stop contamination without using chemicals.

I could go on and on about my many concerns regarding this, but I will end with my proposal. I propose that there should be an exemption for farms that sell under a certain amount of produce each year. It is important that the conventional farms begin to be held accountable for the merchandise they are selling. I think this is great for them. Most illness and deaths from food is due to conventional farms. However, I feel that small farms who sell locally should be exempt.
overall, I do not feel that, as the rules are worded right now, it will affect whom it should be affecting. I feels as though we are playing a game of monopoly here. And we are doing so in the guise of making food more safe. We are making it impossible for organic to even be an option. Organic and local farming is Conventional farmings only real competitor. The government has been backing the side of the factory farms for a long time. It almost seems as though this new Act, as well as the new Rules, are really just another way to put the factory farms competitors out of business, while appealing to the uninformed publics desire to have safer food. In reality the food will no longer even be food, the soil will no longer be soil. And we really should take a minute also to consider what this will be doing to the ecosystem to local farms who will be put out of business and/or have to change their ways. Animals are not making us sick in those situations, and yet changing that will make them sick. If this goes into effect, our food supply will be changed greatly. What will be eating eating is known cancer-agent chemicals mixed in with what appears to be food. And I for one will not accept that as okay.

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Environmental Impact Statement (EIS) for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Comment On: FDA-2014-N-2244-0007
Draft Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Notice for Public Meeting on Draft Environmental Impact Statement

Document: FDA-2014-N-2244-DRAFT-0369
Comment from Anonymous Anonymous, NA

Submitter Information

Name: Anonymous Anonymous
Organization: NA

General Comment

It is a great idea to implement regulations on agricultural water, BSA of animal origin, domesticated animals, but how is this fully going to be regulated? There will be regulations on agricultural water but what happens when it rains? Will rain water be examined for possible microorganisms or viruses? Also, domesticated animals should not be near produce even if it is covered because that does not guarantee that no contamination will occur. How will this even be regulated when farmers are too busy working; they won't have time to notice if a domesticated animal does contaminate the crops. How often will anyone have to check for that and how will it go into records?

RECIRCULATING FARMS COALITION
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March 11, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2014-N-2244
Comments on the Draft Environmental Impact Statement for the Proposed Rule, Standards for the Packing and Holding of Produce for Human Consumption

To Those at the Food and Drug Administration:

On behalf of the Recirculating Farms Coalition ("RFC")[1] and our members, please accept this letter as formal comments on the Draft Environmental Impact Statement ("DEIS") for the Food and Drug Administration's ("FDA") proposed rule for "Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, Produce Rule" ("Produce Rule").

In addition to these comments, RFC incorporates by reference all of the comments that it has already submitted on the Produce Rule, and the Proposed Amendments to the Produce Rule.

Specifically, RFC offers comments that urge the final EIS account for the environmental impacts this rule can have on emerging agricultural sectors. We ask that the FDA become more familiar with the urban agriculture and recirculating farming industries, as they are growing nationwide and contribute to the overall sustainability of our country's food system. As such, it is not effective or appropriate to simply exclude them from the requisite environmental impact assessment that must be done prior to the final implementation of the Produce Rule.

Further, RFC requests that the FDA's final EIS specifically state that its environmental assessment of the Produce Rule's Agricultural Water and Soil provisions excludes recirculating farms because the nature of these operations does not make them subject to compliance with these sections of the proposed Produce Rule.

[1] The Recirculating Farms Coalition is a national non-profit collaborative group of farmers, educators, non-profit organizations and many others committed to building local sources of healthy, accessible food,

I. Background

The Recirculating Farms Coalition works with growers throughout the United States who use nutrient rich, naturally cleaned and constantly recycled water in place of soil as the basis to grow food and other agricultural products. These “recirculating” farmers employ “hydroponics” – growing plants in recirculating nutrient rich water, “aquaculture” – raising fish on land, in tanks with recirculating water (similar to an aquarium type design) and “aquaponics” a combination of hydroponics and aquaculture where fish and plants are raised together in one closed-loop symbiotic recirculating system.

Recirculating farms are currently operating successfully throughout the United States and in many other countries. In fact, recirculating technology has been developing for over 35 years in the United States. Researchers, scientists and farmers are continually refining techniques and methods to increase production, profitability and environmental sustainability. Facilities across the country, and around the world are conducting research and implementing new ways to further improve and expand these farms.

Recirculating farms may be indoors, like in a greenhouse or other structure, or outside, depending on the climate. Their main feature is that the water used is continuously filtered and recycled, then circulated throughout the farm.

These farms are mostly closed-loop operations. Their contained nature makes it more difficult for pests and contaminants from outside the farm to get in, so often these systems can operate without antibiotics, and other drugs or chemicals.

Recirculating hydroponics, aquaculture and aquaponic farms also need not be connected to natural waters to source or drain water. Being closed-loop means that whatever is in the farm system is unlikely to escape.

These farms can also rely largely on renewable energy, like solar, wind and geothermal power, or repurposed energy like methane gas generated from waste and previously used vegetable oil, to heat, light or otherwise power the farm.

Recirculating farms can be completely contained systems that re-use most of their water. There are a number of filtration methods to remove waste; the filtered water is then recycled back throughout the system. Ideally, farms only replace very small percentages of the total water volume, due to some loss during waste removal and/or evaporation

Researchers and industry experts are developing a variety of resourceful ways to deal with farm by-products, such as creating feed ingredients for other fish or shellfish (which would naturally consume such products in the wild). Some farms re-purpose waste into fertilizer for soil-based plants.

These farms are scalable too — they can be as compact as a desktop, for personal use, or larger, for a commercial operation. Being versatile in shape and size and self-contained

allows these farms to be located within the communities that will use the products. This cuts down on use of fuel for transport and gives consumers fresher food.

New recirculating farms are popping up all around the United States, and these farms are continuously working to increase their safety, efficiency, and environmental sustainability. The industry should not be penalized for their unique and innovative practices by being grouped in with other farming techniques with different inherent risks. However, in yet another step in the development and implementation of the food safety modernization act, the FDA has not accounted for the important ecologic, social and economic role of recirculating farms in the United States

As the FDA is surely aware, the National Environmental Policy ACT ("NEPA") requires it to issue an Environmental Impact Statement ("EIS"), which is a "detailed statement . . . on the environmental impact of the proposed action, any adverse environmental effects which cannot be avoided should the proposal be implemented, [and] alternatives to the proposed action . . . [,]" among other disclosures.[2] These sweeping policy goals are realized through a set of "action forcing" procedures that require agencies to take a "hard look" at the environmental consequences of their actions.[3] Under NEPA, if a draft EIS "is so inadequate as to preclude meaningful analysis, the agency *shall* prepare and circulate a revised drafted of the appropriate action."[4]

In light of NEPA's statutory requirements, please find RFC's comments below on the deficiencies of the proposed DEIS for the Produce Rule in its current form.

II. The DEIS does not evaluate how the produce rule will impact the United States' growing urban agriculture sector.

The DEIS's NEPA analysis is completely void of addressing how the Produce Rule will impact urban farms and their surrounding cultural, socioeconomic and ecological environment. Without doubt, in the spirit of U.S. entrepreneurism, diverse forms of urban agriculture operations continue to emerge in cities across the United States. Many of these businesses employ some form of hydroponic, aquaponic and aquaculture growing techniques.[5]

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[2] 43 U.S.C. § 4332(2)(C) (2006).
[3] *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989).
[4] 40 C.F.R. § 1502.9(a)(emphasis added).
[5] *See e.g. Study to examine trends in urban agriculture*, PENN STATE NEWS, (Aug. 17, 2012), http://news.psu.edu/story/147385/2012/08/17/study-examine-trends-urban-agriculture (recognizing that "[u]rban agriculture also is diverse in production methods. For example, crops may be grown in vacant lots, on rooftops, by hydroponic methods (growing plants without soil) or in high tunnels (a type of greenhouse; also known as hoop houses), among others."); *see Board of Health Policy Regulations for Urban Agriculture in Somerville*, http://www.somervillema.gov/sites/default/files/All-Three.pdf (last visited Mar. 13, 2015)(including hydroponic and aquaponic farms in the definition of farming in municipal regulations); *A Summary of Urban Agriculture Amendments to Detroit's Zoning Ordinance*, http://www.law.msu.edu/clinics/food/busdickerfact.pdf (last visited Mar. 13, 2015)(including specific definitions for hydroponic, aquaponic and aquaculture urban agriculture initiatives in Detroit).

The North American Urban Agriculture Committee defines urban agriculture as "the production, distribution and marketing [and disposal] of food and other products within the cores and edges of metropolitan areas. Urban agriculture is a complex activity, addressing issues of food security, neighborhood development, environmental sustainability, land use planning, agricultural and food systems, farmland preservation, and other concerns."[6] It has becoming increasingly accepted that urban farms can improve the environment, reduce greenhouse emissions, and improve access to healthy, locally grown food.[7] The U.S. Environmental Protection Agency ("EPA") also recognizes that "other possible benefits include promoting health and physical activity, increasing community connections, and attracting economic activity."[8] Furthermore, the Food and Agriculture Organization of the United Nations ("FAO") has identified these additional contributions of urban agriculture to a region's overall food security:

- Locally produced food requires less transportation and refrigeration, it can supply nearby markets with fresher and more nutritious products at competitive prices.
- Consumers - especially low-income residents - enjoy easier access to fresh produce, greater choice and better prices.
- Vegetables have a short production cycle; some can be harvested within 60 days of planting, so are well suited for urban farming.
- Garden plots can be up to 15 times more productive than rural holdings. An area of just one square metre can provide 20 kg of food a year.
- Urban vegetable growers spend less on transport, packaging and storage, and can sell directly through street food stands and market stalls. More income goes to them instead of middlemen.
- Urban agriculture provides employment and incomes for poor women and other disadvantaged groups.
- Horticulture can generate one job every 100 square meter garden in production, input supply, marketing and value-addition from producer to consumer.[9]

Neither the Produce Rule, nor its DEIS, distinguish or recognize that a growing and significant quantity of food is being cultivated by urban entities that will likely be covered by the Produce Rule.

RFC recognizes that currently little data exists that quantifies the social, environmental and economic impact of urban agriculture within the United States. In fact, the United States Department of Agriculture's National Institute of Food and Agriculture recently awarded a nearly half million-dollar research grant to examine the trends in urban farming.[10] Nevertheless, it is incumbent upon the FDA to recognize the growing

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[6] *Frequent Questions*, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, http://www.epa.gov/brownfields/urbanag/frequent.htm (last visited Mar. 13, 2015).
[7] *See e.g. Urban Agriculture & Improving Local, Sustainable Food Systems*, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, http://www.epa.gov/brownfields/urbanag/ (last visited Mar. 13, 2015).
[8] *Id.*
[9] *Urban Agriculture*, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, http://www.fao.org/urban-agriculture/en/ (last visited Mar. 13, 2015).
[10] *Study to examine trends in urban agriculture*, *supra* note 5.

importance of urban agriculture in its EIS because the implementation of the Produce Rule could have significant environmental impacts on the longevity of this important sector in U.S. agriculture.

Urban agriculture operations face distinct challenges and opportunities compared to their rural counterparts, none of which are accounted for within the Produce Rule's DEIS. They have unique food safety concerns, and their relationship to water, biological, ecological and soil resources differ significantly from rural operations. Urban farms contribute significantly to the reduction of cities' waste, greenhouse gas emissions, and health disparities. The potential loss of urban farming enterprises because of produce rule's impact could have serious and detrimental environmental ramifications on the communities who depend on these local food sources. Consequently, the final EIS must address this deficiency in order to fully comply with NEPA.

III. The DEIS Fails to Address Aquaponic and Hydroponic Farms.

A. Summary of Differences

As RFC explained in previous 2013 and 2014 comments on the Produce Rule (developed from comments submitted by the Chicago Food Policy Council) recirculating farms are distinctly different from soil-based growing operations. Produce grown via covered aquaponics and hydroponics or even those in more open systems, are not exposed to the same risk factors as produce grown in the ground of outdoor fields. Produce grown in fields can become contaminated from a variety of sources, including mammalian manure used as fertilizer, contaminated surface and ground water used to irrigate plants, in processing or from other sources, and contact with birds, insects, cats, dogs, deer, and livestock carrying human pathogens, and previously-contaminated soil, among other concerns.[11] In contrast to conventional field farming, recirculating farming minimizes the risk of human pathogen transmission because (1) fish are inherently different than mammalian or avian species and do not carry the suite of pathogens responsible for the majority of foodborne illness, and (2) operation of recirculating systems involves numerous safeguards within in a closed loop system.[12] Additionally, these farms are raised from the ground and often protected by various methods of enclosure and cover.

In recirculating aquaponics and hydroponics, water is not applied directly to the harvestable portion of the plants. Rather, the water directly contacts the roots of the plants, which act as biofiltration systems that filter the water before it is recirculated back to the rest of the system. Often, a barrier separating the harvestable portion of the plants from the water minimizes the likelihood that contamination will occur.[13] In fact, FDA has recognized that indirect methods of water application -- such as those used in aquaponic

[11] R.V. Tauxe, et. al., Evolving Public Health Approaches to the Global Challenge of Foodborne Infections, 139 INT'L J. OF FOOD MICROBIOLOGY S-16, S-20 (2010).
[12] *See id.* at S17-18
[13] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Fed. Reg.3504, 3523 (Jan. 16, 2013) (proposed for codification at 21 C.F.R. pts. 16 and 112).

and hydroponic systems -- are less likely to contaminate produce than water applied by direct methods.[14]

In aquaponics, water circulated through the system must be of good quality to maintain the health of the fish in the tanks.[15] Aquaponic systems also have natural biofiltration systems, in which fish waste metabolites are removed by nitrification and direct uptake of the plants. Water absorbed through plant roots eventually flows back to the fish tanks for reuse.[16] Water used in aquaponic systems most often comes from public drinking water systems, which "have the lowest relative likelihood of contamination due to existing standards and routine analytical testing."[17] An aquaponic system can fail if any of the various components become unbalanced: dissolved oxygen, carbon dioxide, ammonia, nitrate, nitrite, pH, chlorine, stocking density of the fish, growth rate of the fish, feeding rate and volume, and related environmental fluctuations.[18]

Additionally, and perhaps most notably, fish are not high-probability vectors of diseases to humans.[19] Human enteric pathogens responsible for the majority of foodborne illnesses survive primarily in warm-blooded mammals and not in cold-blooded animals such as fish. E. coli and Salmonella, the two human pathogens of greatest concern to FDA, are not present in fish manure.[20] E. coli is transmitted only by mammals, with cattle serving as carriers of the O157:H7 serotype and other mammals such as pigs, dogs, cats, rabbits, goats, and sheep carrying various other serotypes.[21] Primarily mammals such as poultry, cattle, sheep, and pigs carry salmonella.[22] Fish tissue may become contaminated with Salmonella if they are exposed to water containing bird or mammal manure containing Salmonella, yet fish do not carry Salmonella or E. coli in their gut as mammals do.[23] FDA itself has recognized that the best indicator human pathogen risk is testing for "non-pathogenic microorganisms that are commonly found in the intestines of warm-blooded animals."[24]

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[14] *See id.* at 3523.
[15] Steve Diver and Lee Rinehart, Aquaponics – Integration of Hydroponics with Aquaculture, ATTRA (NCAT/Nat'l Sustainable Agric. Info. Service) 2006, updated 2010, at 1.
[16] James Rakocy, Donald Bailey, R. Charlie Schultz, Eric Thoman, Update on Tilapia and Vegetable Production in the UVI Aquaponic System, 676-690, New Dimensions on Farmed Tilapia: Proceedings of the Sixth International Symposium on Tilapia in Aquaculture (2004).
[17] 78 Fed. Reg. at 3523.
[18] Diver, *supra* note 15, at 3.
[19] J. Hollyer, et al., On-Farm Food Safety: Aquaponics, 38 FOOD SAFETY AND TECH. J. 1 (July 2009).
[20] *See* R.V. Tauxe, supra note 11, at S17
[21] M.D. Sobsey., L.A. Khatib, V.R. Hill, E. Alocilja, S. Pillai, Pathogens in Animal Wastes and the Impacts of Waste Management Practices on their Survival, Transport, and Fate. NATIONAL CENTER FOR MANURE AND ANIMAL WASTE MANAGEMENT PUB. NO. 913C0306 (USDA NIFA Fund for Rural America Grant) 2006 at 620.
[22] *Id.* at 623.
[23] İlkan Ali Olgunoğlu, Salmonella in Fish and Fishery Products, in SALMONELLA -A DANGEROUS FOODBORNE PATHOGEN (Dr. Barakat S M Mahmoud, Ed., 2012).
[24] 78 Fed. Reg. at 3561.

Fresh leafy greens grown in fields have been responsible for many outbreaks of E. coli O157:H7 and Salmonella infections in the United States.[25] E. coli and Salmonella pathogens may be transferred to the harvested produce by field animals, mammalian manure application, or contaminated surface and ground waters. As none of these risk factors are present in aquaponic or hydroponic recirculating closed-loop systems, these methods of farming greatly minimize the risk of E. coli or Salmonella contamination of produce.

Recirculating farms are different, by their very nature, than other forms of field soil-based agriculture. Nevertheless, the DEIS completely fails to recognize the differences between soil and water based agriculture in its environmental impact assessment of the proposed agricultural water rule. By failing to incorporate these differences into the overall framework of the DEIS, it is deficient in meeting its legal requirements of NEPA, which mandate a full environmental review of the potential impacts of the Produce Rule.

RFC recognizes that little data that quantifies the social, environmental and economic impact of recirculating farms within the United States. Our organization is currently working to compile a map of the many recirculating farms throughout the country, and would be willing to share our research should it be helpful to the FDA to fulfill its NEPA obligations.

Nevertheless, RFC suggests that the finalization of the FDA's EIS must incorporate recirculating farming into its understanding of agricultural production in the United States. Excluding these operations creates and flawed assessment of the Produce Rule's potential environmental impacts.

B. The DEIS' assessment of the produce rule's "agricultural water" provision should specifically exclude aquaponic and hydroponic systems.

First, water containing fish waste fertilizer is not intended or likely to come into contact with the harvestable portion of the plants. Second, fish waste does not contain E. Coli, and therefore the microbial testing proposed by FDA is inapplicable to water used in aquaponic systems.

The water used to irrigate the plant roots in aquaponic and hydroponic systems does not fall within FDA's definition of "agricultural water." FDA defines "agricultural water" as "water that is intended to, or likely to, contact the harvestable portion of covered produce" or food contact surfaces, including water used in growing activities and in harvesting, packing, and holding activities.[26] FDA's guidance indicates that agricultural water is intended to encompass water used for overhead spray irrigation but not water

[25] *See e.g. Leafy Greens Safety Initiative Continues* (2nd Year), FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/Food/FoodborneIllnessContaminants/BuyStoreServeSafeFood/ucm115898.htm (last modified 2013) (last accessed Mar. 13, 2015); *see also* R.V. Tauxe, supra note 11, at S19 (explaining that salad greens, lettuce, sprouts, and melons were the types of produce most often associated with norovirus, Salmonella, and E. coli
O157:H7)

[26] *See* 78 Fed. Reg. at 3630 (proposed 21 C.F.R. § 112.3(c)).

used for root irrigation.[27] In fact, FDA states that "indirect water application methods would not be subject" to the Produce Rule.[28]

Aquaponic and hydroponic systems are designed such that the nutrient-rich water targets only the roots of the plants and not the edible portions of the produce. In addition, water containing fish and fish waste is never used for washing or cooling harvested produce in these systems. Instead, a large number of aquaponic and hydroponic farmers use water from Public Water Systems, as defined under the Safe Drinking Water Act regulations, 40 CFR Part 141, to spray on and wash produce after harvest. FDA has provided an exemption to the agricultural water testing requirements for use of public drinking water supplies.[29] For these reasons, water used in aquaponics or hydroponics is not "agricultural water."

Additionally, FDA has proposed to require regular microbial testing for generic E. coli of all agricultural waters at a frequency that reflects the risk of contamination.[30] FDA has concluded that generic E. coli is the best microbial indicator of water quality for the purpose of pathogen testing of agricultural water. As established in above, E. coli and human pathogens are unlikely to be present in water circulated through aquaponic and hydroponic systems. Because it is highly unlikely that water circulated through aquaponic and hydroponic systems would be contaminated with E. Coli, there is not any science-based or risk-based justification for applying the Agricultural Water Standards to aquaponic or hydroponic recirculating farming.

However, the DEIS does not acknowledge the differences amongst soil and water based growing when it assesses the affected environment, environmental impacts, cumulative impacts, and potential irretrievable and irreversible impacts of the agricultural water provision. RFC suggests the final EIS **specifically state that its analysis of the environmental impact from the Produce Rule's agricultural water provision excludes water based growing operations because these operations do not fall under the agricultural water provision.**

C. Recirculating farms should not be subject to the Biological Soil Amendments.

The amendments for the Produce Rule, Subpart F – Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste ("Soil Standards") do not contemplate the nature of aquaponic or hydroponic farming and, as written, is inapplicable to recirculating farming systems. RFC requests that final EIS specifically recognize that its environmental assessment of the Produce Rule's Soil Standard Provision does not include aquaponic and hydroponic systems.

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[27] *See id.* at 3563. FDA explains that "water used for drip or furrow irrigation in apple orchards would not be considered agricultural water because the water is unlikely to contact the harvestable portion of the crop." *Id.* Drip or furrow irrigation used in apple orchards involves application of water to the root zones only.
[28] *Id.*
[29] *See* 78 Fed. Reg. at 3570 (proposed 21 C.F.R. § 112.45).
[30] *Id.* at 3560 (proposed 21 C.F.R. § 112.45(a)).

It seems that FDA did not intend to regulate aquaponic and hydroponic farming via the Soil Standards. FDA defines "soil amendment" as "any chemical, biological, or physical material (such as elemental fertilizers, humus, manure, non-fecal animal products, peat moss, perlite, pre-consumer vegetative waste, agricultural tea and yard trimmings) intentionally added to the soil [emphasis added] to improve the chemical or physical condition of soil in relation to plant growth or to improve the capacity of the soil to hold water."[31]

Aquaponic and hydroponic systems do not utilize soil at all and therefore should be specifically exempted from the proposed regulations. While the Soil Amendments would not apply to aquaponic and hydroponic growing methods, we request that the final EIS be extremely clear by stating aquaponics and hydroponics are exempted from the Soil Standards, and therefore not subject to environmental review under NEPA.

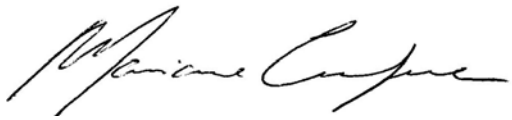
IV. Conclusion

The Recirculating Farms Coalition and its members share FDA's goal in making informed environmental decisions in its effort to minimize instances of foodborne illness related to the growing, harvesting, packing, and holding of produce.

For the reasons set forth above, we respectfully request that FDA to develop a more robust EIS before finalization that addresses the produce rule's environmental impact on urban environments, urban agriculture operations and recirculating farms.

We appreciate your review of our comments and look forward to working with FDA in promoting a safe, sustainable food production system in the U.S.

Sincerely,



Marianne Cufone, Executive Director
Emily Posner, Policy and Legislative Counsel

[31] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Fed. Reg. 3504, 3548 (Jan. 6, 2013) (proposed for codification at 21 C.F.R. pts. 16 and 112).

Comments to FDA-2014-N-2244 Draft EIS due 3.13.2015

Urban agriculture is not addressed for large cities like the City of Los Angeles. Sources of water are not from natural streams or rivers, but from treated wastewater. Though regulated on a State level for the Federal Clean Water Act, Water Rights have been accessed outside the adjudicated Groundwater Basin to entities that have no obligation for MS4 permit compliance outside an individual NPDES permit.

State of California Strategic Growth Council has granted State Proposition 84 Urban Greening Planning Grant Program funds for Urban Agriculture Plans.

Urban Agriculture includes cultivation, processing and distribution. Local grown food is preferred by the Hotel and Tourism industry.

Treated water sent to a US receiving water body such as the LA River should be addressed in this regulation. It is not.

Please expand the scope to include this new market.

Joyce Dillard
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PUBLIC SUBMISSION

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Environmental Impact Statement (EIS) for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Comment On: FDA-2014-N-2244-0007
Draft Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Notice for Public Meeting on Draft Environmental Impact Statement

Document: FDA-2014-N-2244-DRAFT-0358
Comment from James Gordon, Cowlitz Indian Tribe

Submitter Information

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Submitter's Representative: James Gordon - Cultural Resources Technician
Organization: Cowlitz Indian Tribe

General Comment

To Whom It May Concern:

Docket # FDA-2014-N-2244

Given that the above-referenced project is within the Cowlitz Tribe's area of concern, the Cultural Resources Department of the Cowlitz Indian Tribe would like to state its interest.

In the event of ground-disturbing activity, the Cowlitz Indian Tribe recommends an Inadvertent Discovery Plan be attached to the permit; we have included language for your consideration.

This determination is based on all currently available knowledge, and is subject to revision should new information arise. Please contact us with any questions or concerns you may have. We look forward to working with you on this undertaking.

Thank you for your time and attention.

All My Relations,

dAVe burlingame
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COWLITZ INDIAN TRIBE
INADVERTENT DISCOVERY LANGUAGE

[revised 130222]

In the event any archaeological or historic materials are encountered during project activity, work in the immediate area (initially allowing for a 100' buffer; this number may vary by circumstance) must stop and the following actions taken:

1. Implement reasonable measures to protect the discovery site, including any appropriate stabilization or covering; and 2. Take reasonable steps to ensure the confidentiality of the discovery site; and, 3. Take reasonable steps to restrict access to the site of discovery.

The project proponent will notify the concerned Tribes and all appropriate county, state, and federal agencies, including the Department of Archaeology and Historic Preservation. The agencies and
Tribe(s) will discuss possible measures to remove or avoid cultural material, and will reach an agreement with the project proponent regarding actions to be taken and disposition of material.

If human remains are uncovered, appropriate law enforcement agencies shall be notified first, and the above steps followed. If the remains are determined to be Native, consultation with the affected Tribes will take place in order to mitigate the final disposition of said remains.

See the Revised Code of Washington, Chapter 27.53, "Archaeological Sites and Resources," for applicable state laws and statutes. See also Washington State Executive Order 05-05, "Archaeological and Cultural Resources." Additional state and federal law(s) may also apply.

It is strongly encouraged copies of inadvertent discovery language/plan are

retained on-site while project activity is underway.

Contact information:

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March 13, 2015

Leslie Kux
Associate Commissioner for Policy
U.S. Food and Drug Administration
5630 Fishers Lane Rm 1061
Rockville, MD 20852
Docket No: FDA-2014-N-2244

Comments Re: Draft Environmental Impact Statement on Food Safety Modernization Act (FSMA) Produce Rule

To the United States Food and Drug Administration (FDA):

Center for Food Safety (CFS) submits the following comments on behalf of itself and its members in response to FDA's Draft Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 1852 (January 14, 2015).

CFS is a nonprofit, public interest advocacy organization dedicated to protecting human health and the environment by curbing the proliferation of harmful food production technologies and promoting organic and sustainable agriculture. As a membership organization, CFS represents nearly 600,000 farmer and consumer members who reside in every state across the country, and who support safe, sustainable food systems.

The U.S. Food and Drug Administration's (FDA, or "the agency") Draft Environmental Impact Statement (EIS) on the proposed Food Safety Modernization Act (FSMA) Produce Rule fails to adequately assess the potential impacts of the Rule's implementation. The National Environmental Protection Act (NEPA) requires federal agencies to provide a comprehensive assessment of potential long- and short-term impacts that may result from new rules. FDA's draft EIS instead takes a narrow approach to assessing impacts and relies heavily on unfounded assumptions and speculation. FDA regulations require that, in assessing the significance of impacts on the human environment, the agency must consider short-term effects, local effects, and individually insignificant effects that may have a cumulative impact. Despite this requirement, the agency's EIS considers a narrow interpretation of significance that does not account for these assessments. This falls short of what NEPA requires. It is unsurprising then

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that by omitting the broader scope that is required the agency has determined the proposed rule to have "no significant impact."

Legal Background: National Environmental Policy Act

NEPA is "our basic national charter for protection of the environment."[1] NEPA emphasizes the importance of comprehensive environmental analysis to ensure that federal agencies make informed decisions, and requires federal agencies to assess the environmental consequences of their actions before those actions are undertaken. NEPA "ensures that the agency . . . will have available, and will carefully consider, detailed information concerning significant environmental impacts; it also guarantees that the relevant information will be made available to the larger [public] audience."[2]

NEPA also established the Council on Environmental Quality (CEQ).[3] The regulations subsequently promulgated by CEQ[4] implement the directives and purpose of NEPA, and "[t]he provisions of [NEPA] and [CEQ] regulations must be read together as a whole in order to comply with the spirit and letter of the law."[5] CEQ's regulations are applicable to and binding on all federal agencies,[6] and are entitled to "substantial deference," *see, e.g.*, *Andrus v. Sierra Club*, 442 U.S. 347, 358 (1979). Among other requirements, CEQ's regulations mandate that federal agencies address all "reasonably foreseeable" environmental impacts of their proposed programs, projects, and regulations.[7] This must include analyses of direct, indirect, and cumulative effects.[8] The assessment must be a "hard look" at the potential environmental impacts of its action.[9]

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[1] 40 C.F.R. § 1500.1(a).

[2] *Robertson v. Methow Valley Citizens Council,* 490 U.S. 332, 349 (1989) (emphasis added).

[3] *See* 42 U.S.C. §§ 4321, 4344.

[4] 40 C.F.R. §§ 1500-1508.

[5] *Id*. § 1500.3.

[6] *Id*. §§ 1500.3, 1507.1; *see, e.g., Hodges v. Abraham*, 300 F.3d 432, 438 (4th Cir. 2002).

[7] *See* 40 C.F.R. §§ 1502.4, 1508.8, 1508.18, 1508.25.

[8] *See id*. §§ 1508.8, 1508.9, 1508.13, 1508.18.

[9] *Blue Mountains Biodiversity v. Blackwood*, 161 F.3d 1208, 1211 (9th Cir. 1998); *Nat'l Parks & Conservation Ass'n v. Babbitt*, 241 F.3d 722, 731 (9th Cir. 2001) (quoting 40 C.F.R. § 1508.27).

NEPA requires federal agencies to prepare an EIS for all "major Federal actions significantly affecting the quality of the human environment."[10] An EIS balances "different kinds of positive and negative environmental effects, one against the other" and "weighs negative environmental impacts against a project's other objectives."[11] "Preparation of an EIS thus ensures that decision-makers know that there is a risk of significant environmental impact and take that impact into consideration."[12] FDA's decisions incorporated into and flowing from the EIS must be "complete, reasoned, and adequately explained."[13]

Federal agencies cannot segment or manipulate the scope of their actions in order to avoid a finding of significance and evade the full environmental impact study NEPA demands. *See, e.g.*, *Coalition on Sensible Transportation v. Dole*, 826 F.2d 60, 68 (D.C. Cir. 1987); 40 C.F.R. 1508.27(b)(7) ("Significance cannot be avoided by … breaking [an action] down into small component parts."). Under CEQ regulations, FDA must consider "connected, cumulative, and similar actions" together when determining the scope of its environmental review under NEPA. These regulations are designed to prevent an agency from "dividing a project into multiple 'actions,' each of which individually has an insignificant environmental impact, but which collectively have a substantial impact." 40 C.F.R. § 1508.25*; see Earth Island Inst. v. U.S. Forest Serv*., 351 F.3d 1291, 1305 (9th Cir. 2003)*, citing Thomas v. Peterson*, 753 F.2d 754, 758 (9th Cir. 1985); *Native Ecosystems Council v. Dombeck*, 304 F.3d 886, 893-94 (9th Cir. 2002). These requirements apply to Environmental Assessments and EISs alike. *See, e.g.*, *Klamath-Siskiyou Wildlands Center v. Bureau of Land Management*, 387 F.3d 989, 998 (9th Cir. 2004).

The EIS fails to consider local or regional effects.

Assessing impact significance only at the national scale ignores certain impacts to water, soils, biological and ecological resources, air, and human health that may be locally significant. For example, the EIS determines that the requirement in Subpart F on Biological Soil Amendments (BSAs) that establishes a 45-day waiting period for application might also cause farmers to switch to using chemical fertilizers.[14] Despite this, the agency concludes that the impacts of switching to chemical fertilizers will have no significant impact because only a small

[10] 42 U.S.C. § 4332(2)(C).

[11] *Sierra Club v. Marsh*, 769 F.2d 868, 875 (1st Cir. 1985).

[12] *Anderson*, 314 F.3d at 1022.

[13] *Northwest Coal. for Alts. to Pesticides v. EPA*, 544 F.3d 1043, 1052 n.7 (9th Cir. 2008).

[14] U.S. Food and Drug Administration. *Draft Environmental Impact Statement (EIS) for the Proposed Rule: Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.*" January 9, 2015, at 4-52.

percentage of farmers currently use BSAs nationally. This ignores the fact that the farms using BSAs may be locally concentrated, and the impacts of increased use of chemical fertilizers may be incredibly significant at the local or regional level.

The EIS consistently fails to consider local impacts as significant or assess local level impacts altogether. In regards to air quality impacts, the EIS states that "Nationwide, the net generation of criteria pollutants and other greenhouse gases are not expected to change considerably as a result of finalizing the [Produce Rule]."[15] By defining significance as nationally impactful, the EIS ignores that impacts to air quality may be locally or regionally significant. Similarly, FDA states that cumulative impacts to biological resources are difficult to predict on a nationwide basis. The agency acknowledges that impacts to biological and ecological resources may be localized, e.g., species in local watersheds may be adversely impacted, but goes on to state that "FDA does not anticipate significant impacts to biological and ecological resources."[16] To determine that possible adverse impacts are insignificant because they are localized is inconsistent with a thorough environmental impact assessment. Without adequate consideration of locally- or regionally-scaled impacts the EIS fails to fulfill the requirements of NEPA and the FDA's determination of "no significant impact" is unsupported.

The EIS fails to consider short-term impacts.

In assessing the impacts from the agricultural water standard (Subpart E) and the biological soil amendments standard (Subpart F), the EIS acknowledges that the Rule could lead to an increase in chemical water treatments[17] and in the use of chemical fertilizers,[18] respectively. Despite this potential increase in chemical application to the environment, the EIS determines that neither will have significant environmental impact because any effects would be limited to the short-term. FDA's analysis of Subpart E, for example, acknowledges that the Rule may cause farmers to use chemical treatments to come into compliance, but considers increased chemical use to be insignificant because the effects may not be permanent.[19] The impermanence of potential effects does not necessarily dictate their significance, especially when locally specific factors are considered, such as proximity to wetlands, marshes or other sensitive water resources. Toxic synthetic inputs can leach into air and water, creating acute

[15] EIS at 5-22.

[16] EIS at 5-20.

[17] EIS at 4-18, 4-21, 4-37, 4-39.

[18] EIS at 4-57.

[19] EIS at 4-39.

health threats for local communities in the short-term. Yet, these impacts are not considered significant in the EIS.

In regards to the agency's analysis of Subpart I on wild and domesticated animal standards, FDA acknowledges that the requirement for producers to wait an appropriate period for harvesting after intrusion of domesticated animals on crop areas will result in more concentrated livestock and therefore soil compaction and more concentrated waste runoffs. Despite this, the agency determines that these impacts are not significant because they are short term. FDA also states that requiring farmers to wait an appropriate period to harvest produce after wild animal intrusion may increase the use of rodenticides and other chemical deterrents to exclude wildlife. Again, FDA considers the impacts from increased chemicals used to manage wild animals to be short-term and therefore does not consider them significant.

In fact, soil compaction, concentrated waste, and increased chemical use are all significant environmental hazards that could have direct adverse impacts on water, soils, and ecological and biological resources despite their temporal reality. This may be especially true, for example, if the concentrated livestock are routinely treated with antibiotics, which can enter local environments from animal wastes and promote the spread of antibiotic resistant bacteria.[20] The concentration of animal wastes may be a short-term issue, but the impacts from the runoff of wastes with high prevalence of bacteria resistant to medically-important antibiotics are much longer lived and certainly significant. The EIS's failure to consider impacts as significant solely on the grounds that they may not be permanent is an insufficient assessment of environmental impacts and falls short of NEPA requirements.

The EIS fails to consider cumulative impacts.

NEPA prohibits agencies from separately assessing the individual components of a project to determine whether effects are significant. Instead, a sound environmental impact analysis must also consider the collective impact of all connected actions of a project. In the EIS, the agency's only effort to unify its segmented analysis merely summarizes the individual impacts rather than providing a comprehensive assessment of the Rule in its entirety. Failing to account for the potential cumulative impacts to water, soil, ecological and biological resources,

[20] Various published studies not limited to: Slibergeld, Ellen K., Jay Graham, & Lance B. Price. "Industrial Food Animal Production, Antimicrobial Resistance, and Human Health." *Annu. Rev. Public Health, 29*. 151-169. (2008); Chee-Sanford, Joanne C. "Fate and Transport of Antibiotic Residues and Antibiotic Resistance Genes following Land Application of Manure Waste." *J Environ. Qual., 38*. 1086-1108. (2009); Hayes, J.R. et al. "Multiple-Antibiotic Resistance of *Enterococcus* spp. Isolated from Commercial Poultry Production Environments," *Applied and Environmental Microbiology*, *70(10)*. October 2004: 6005-6011; Yong-Guan, Z. et al. "Diverse and abundant antibiotic resistance genes in Chinese swine farms," *Proceedings of the National Academy of Sciences of the United States of America, 110(9)*. February 26, 2013.

air, and human health from all aspects of the Rule effectively ignores a substantial requirement of environmental impact assessments. Without this assessment, the EIS is incomplete.

In regards to soils, for example, the separate analyses of Subparts E (agricultural water) and F (BSAs) determine that both could have short-term impacts on soils from increased use of chemicals.[21] In the assessment of Subpart I (wild and domestic animals), the statement finds that soils could also be impacted in the short-term due to increased soil compaction, nutrient run-off, and pesticide use.[22] Despite the potential impacts from three separate standards in the Rule, the EIS's consideration of collective impacts to soils only restates the impacts discussed from Subpart F.[23]

Regarding biological and ecological resources, the EIS similarly acknowledges separate impacts that could potentially emerge from implementation of Subparts E, F, and I, including: increased chemical water treatment degrading surface and groundwater quality[24]; increased chemical fertilizer use and manure runoff[25]; and increased rodenticides, pesticides, land clearing, hunting, trapping, or other disruptions to wildlife habitats, respectively.[26] In the cumulative analysis, though, FDA merely restates individual conclusions and fails to consider the significant impact to biological and ecological resources when all three standards are assessed together. Failing to adequately assess the collective impacts from the Rule violates NEPA, and leads FDA to underestimate the Rule's potential impacts.

FDA misinterprets provisions that "do not authorize or require" certain practices as equivalent to prohibiting those practices.

In certain cases in the EIS, FDA interprets language in the Rule that states a provision does not "authorize or require" as meaning the action is effectively prevented. A prime example of this is the exclusion of wild animals from growing areas. Subpart I on wild and domestic animals establishes the requirement that farms wait an appropriate period to harvest produce after evidence of wild animal intrusion into the growing area. FDA determines that this regulation will have no significant impact on wildlife or threatened and endangered species

[21] EIS at 4-57.

[22] EIS at 4-70.

[23] EIS at 4-90.

[24] EIS at 4-37-38.

[25] EIS at 4-46-48.

[26] EIS at 4-75-76.

because farmers are not required to take measures to exclude wild animals. The EIS states that, "This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages." [27] FDA misinterprets this language as effectively prohibiting such actions and concludes that the provision will prevent farmers from impacting wild and endangered species.

However the provision most certainly does not preclude or prevent farmers from making management decisions that may threaten or kill wild species in order to avoid postponing harvests. FDA even recognizes that farmers may resort to hunting, trapping, poisoning or other destructive tactics in order to prevent animal intrusion, but assumes that local regulatory mechanisms such as permitting requirements would mitigate these actions.[28] Equating a lack of explicit encouragement as effective discouragement ignores the fact that some farmers have already removed conservation areas or wildlife under the mistaken belief that they are at odds with food safety. A 2007 survey of California produce growers found that 88.9% of growers surveyed were using some type of wildlife exclusion practice in response to food safety expectations.[29] FDA cannot assume that in response to required waiting periods growers will not add or increase measures designed to exclude wildlife.

The potential environmental impacts of removing conservation areas and native habitat are substantial. Destroying habitat that borders croplands adversely impacts native pollinators that are crucial to maintaining biodiversity as well as to an abundant, healthy food supply. Over 4,000 species of native bees in the United States depend upon a wide variety of flowers and plants for habitat and forage, and protecting bees and other pollinators is vital to the success of U.S. agriculture.[30] FDA should recognize that the Rule may incentivize farmers to eliminate already sparse wildlife habitat, and appropriately consider the environmental impacts of this practice. However, this scenario is unjustifiably considered unlikely and therefore insignificant in the EIS. FDA's analysis thus does not satisfy the requirements of NEPA.

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[27] EIS at 4-7.

[28] EIS at 4-75.

[29] *See* Center for Food Safety's comments to Docket No. FDA-2011-N-0921 and RIN 0910-AG35, submitted online via regulations.gov November 19, 2013, citing Berreti, M. and Stuart, D. 2008. Food safety and environmental quality impose conflicting demands on Central Coast growers. *California Agriculture, 62(2)*: 68-73.

[30] *See* Center for Food Safety's comments to Docket No. FDA-2011-N-0921 and RIN 0910-AG35, submitted online via regulations.gov November 19, 2013.

The EIS assesses impacts without adequate consideration of all possible actions or measures that may be taken by farmers.

NEPA also mandates that agencies consider all reasonably foreseeable management decisions that may be taken by farmers in response to implementation of the Rule and assess the environmental impacts that could result from each decision. However, throughout the EIS, FDA fails to account for the variety of measures that may be taken. A primary example of this is that, despite the imposition of new and substantial cost burdens of compliance, FDA asserts that the possibility that farmers may choose to close down or switch to crops not covered by the Rule in the face of those costs is unlikely. The environmental impacts of a number of small farms choosing to close down operations or switch crop production are not considered.

In the same vein, while FDA admits that the agricultural water standard could cause farmers to switch from surface water to groundwater,[31] it does not consider the possible impacts from farmers switching to municipal water. In the summary of public comments identified for inclusion in the scope of the EIS, the agency acknowledged that the public raised concerns that the Rule creates a preference for farmers to use groundwater, municipal water, or public water,[32] yet only addresses impacts of switching to groundwater. This ignores the public's expressed environmental concern that, "Switching to municipal water could place an increased demand on already-stressed municipal water supplies."[33] Despite public concern, the environmental impacts of switching to municipal water are not considered in the EIS.

The analysis of the water standard also acknowledges that farmers may increase the use of chemicals to treat water. However, the EIS assumes that the ability of covered farmers to choose other management decisions—such as switching water sources or adding mechanisms to account for microbial die-off[34]—would mitigate any significant impact from increased chemical use.[35] FDA does not provide any basis for assuming either that farmers will choose an alternative management strategy or that doing so would mitigate the impacts from increased chemical treatment. Furthermore, the EIS assumes that growers already using treated BSAs will continue to do so because the proposed rule does not impose a waiting period for application of treated biological materials of animal origin.[36] This ignores other procedural burdens that still

[31] EIS at 4-23.

[32] EIS at 1-29.

[33] EIS at 1-29.

[34] EIS at 4-23 and 4-36. See also 4-27 and 4-37-38.

[35] EIS at 4-23 and 4-36. See also 4-27 and 4-37-38.

[36] EIS at 4-61-62.

apply to treated BSAs and may cause farmers to switch to chemical fertilizers, such as handling and storage requirements.[37] FDA's failure to consider these actions fails to satisfy the requirements of NEPA.

The EIS assumes that related aspects of existing regulations means farmers are already in compliance with those aspects of the Produce Rule and thus expects no significant impacts.

FDA accepts that the existence of the Clean Water Act (CWA); the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); and the Endangered Species Act (ESA) denote compliance with all provisions of the Produce Rule that relate to these regulations. Based on assumed compliance, the EIS determines that minimal or no environment impact will result from the Produce Rule provisions. For example, the EIS relies on CWA regulations to mitigate any impacts from increased chemical runoff, unintentional release of stored manure, and moving livestock to new land that could result from the Rule. The EIS acknowledges that the longer application intervals for untreated BSAs proposed under Alternatives I, III, IV, and V would require longer storage periods for manure, which could result in an increased risk of manure runoff,[38] which may adversely impact water sources or biological and ecological resources. However, the EIS assumes that local and State agencies charged with overseeing nutrient management plans will ensure that BSAs of animal origin are managed in accordance with CWA.[39] In reality this may not be the case, especially considering that CWA is not applicable to most farming activities and its existence is not a guarantee of compliance.

As another example, the EIS concludes that any increase in pesticides resulting from the Rule will have no significant environmental impacts if used in accordance with FIFRA labels. Not only does this fail to account for extra-label or misuse of pesticides, it fails to acknowledge that any use of chemical pesticides is designed to kill or disrupt living organisms. Intentional release of pesticides into the environment poses risks to wildlife, ecosystems, and human health, and use according to their FIFRA labels does not reduce risks to zero. FIFRA does not establish a permitting system for pesticide use or in any way verify their use, but solely regulates registration and labeling.

Similarly, the EIS assumes that farms currently operating under National Pollution Discharge Elimination System (NPDES) permits will prevent significant environmental impacts by merely adhering to the requirements of the permit. However, FDA misunderstands the nature of NPDES permits, which allow for the monitored discharge of pollutants into water sources by permitted facilities. Furthermore, NPDES permits are the exception in U.S.

[37] EIS at 4-61, 4-90.

[38] EIS at 4-45.

[39] *Id.*

agriculture, and only concentrated animal feeding operations (CAFO) are required to apply for NPDES permits. FDA's assessment that farms operating under NPDES permits will prevent significant environmental impacts overestimates the portion of farms the permits represent.

Basing the impact assessment on the assumption that existing compliance and enforcement mechanisms are completely effective fails to address all "reasonably foreseeable" environmental impacts as required by NEPA. FDA cannot pass its responsibilities to adequately regulate under FSMA and to thoroughly consider environmental impacts under NEPA to other agencies. FDA's attempt to do so violates FSMA and NEPA.

Conclusion

Conducting a comprehensive environmental analysis, as required by NEPA, ensures that federal agencies make informed decisions by assessing the environmental consequences of their actions before those actions are undertaken. The FDA's impact assessment for the Produce Rule fails to provide thorough consideration of all reasonably foreseeable environmental impacts and is, therefore, insufficient by NEPA standards. The EIS considers impacts at the local or regional levels and those that may not persist long term as not significant, effectively ignoring the possibility of acute, local effects that may result from the Rule. It also fails to account for multiple plausible actions that may be taken by farmers, both in its assumption that not requiring certain practices is equivalent to prohibiting them and that farmers will choose management decisions that mitigate potential impacts. The EIS further assumes that existing regulatory mechanisms effectively ensure compliance with potentially problematic impacts of the Rule, such as extended manure storage. The analysis of impacts is also conducted in isolation, failing to provide a cumulative assessment of the collective impacts of individual standards. In the absence of addressing these aspects of a truly comprehensive environmental impact assessment, the agency's conclusion that the Rule will have no significant environmental impacts is unfounded. These shortcomings violate NEPA and have resulted in a deficient EIS. FDA must correct these deficiencies before issuing a final Produce Rule.[40]

Thank you for consideration of these comments.

[40] FDA must not construe these comments or any issues raised by other participants in the comment period as grounds for extending the court-ordered deadlines provided in the Consent Decree in Center for Food Safety v. Hamburg. See Consent Decree, Ctr. for Food Safety v. Hamburg, No. 4:12-cv-04529-PJH (N.D. Cal. Feb. 25, 2014). Time for robust comment, thorough NEPA analysis of all reasonably foreseeable impacts on farmers and the environment, and reissuance of the proposed rule have been built into the timeframe established, which requires this rule to be finalized by October 31, 2015. These instances in no way excuse FDA's obligations or constitute "exceptional circumstances" that would warrant FDA to seek an extension of that deadline

Respectfully submitted,

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March 13, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Docket No. FDA-2014-N-2244

To Whom It May Concern:

Food & Water Watch, a nonprofit advocacy organization, appreciates the opportunity to comment on the Draft Environmental Impact Statement (EIS) for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Draft EIS). (Docket No. FDA-2014-N-2244.)

It is appropriate that the FDA did decide to do an EIS for the produce safety rule, given the extent of the environmental impact that can occur due to changes in farm practices that could be triggered by implementation of new standards. While we are not able to offer detailed analysis of each alternative assessed in the Draft EIS, we do have some comments on the assumptions used to assess several areas of impact and suggestions for other resources to include in the determination of impact.

Limited number of management decisions considered

In several areas of the Draft EIS, the most severe consequence of a new requirement that is evaluated is that a farm stops producing a covered crop. We believe this is not a valid assumption of what farmers may do if a new produce safety requirement proves unfeasible for their operation – some operations may not have any other good options for what they can grow or market, and a decision to stop producing a covered crop could be a decision to stop farming. Small acreage farms or those who have developed specific niche marketing may find it too difficult to reorient their operation to no longer grow covered produce. For example, a farm that specializes in heirloom varieties of tomatoes or salad greens will not likely be able to make a shift to noncovered produce like potatoes or to commodity crops and make their operation economically feasible.

The potential for a management decision to exit farming altogether should be evaluated in more of the scopes of the Draft EIS, along with the potential environmental impacts of that decision, including further consolidation of farmland into larger operations or the sale and development of farmland.

Other impacts of a decision to shift to noncovered crops must be more thoroughly assessed, for those who do make that management decision. For example, a shift to crops such as corn or soybeans could also put pressure on local water supplies if the new crop mix

demands more water or has worse soil erosion than the covered products.

Standards directed to agricultural water

Throughout the assessment of impacts from the water standards, FDA assumes very little potential impact from the increased adoption of EPA-approved water treatment technologies. But a consistent theme throughout both rounds of proposed rulemaking on this issue, as well as the Draft EIS, is a lack of information and understanding of what treatment technologies are actually available. The second round of the proposed rule acknowledged this uncertainty and attempted to add more flexibility as one way to address this uncertainty. But it seems premature to definitively state the environmental impacts from management decisions made to meet new water standards, when it is quite unclear what these decisions will actually be. As the state of knowledge on appropriate water testing, pathogen reduction goals and treatment options grows, the impact of management decisions around water will need to be further assessed.

Standards directed to biological soil amendments of animal origin and human waste

One assumption in the assessment of impacts related to management decisions around biological soil amendments is that a shift to more use of commercial fertilizers does not come with its own set of environmental impacts. We would urge FDA to reexamine this assumption. Just yesterday, the U.S. Geological Survey released a report, "Eastern Shore Contributes Excess Nutrients to Chesapeake Bay," that details the burden that historic and current applications of nitrogen and phosphorous – including from commercial fertilizer application – is putting o the health of the Chesapeake Bay. This kind of analysis of the current burden on water quality created by commercial fertilizer use, as well as increases in commercial fertilizer use driven by management decisions triggered by the produc safety rule standards on biological soil amendments must be considered in the final EIS.

Another possible impact of the standards on biological soil amendments could be the loss of opportunity for more farms to shift to a more diverse crop mixture that includes livestock. The trend for beginning farmers, small acreage and direct market focused sectors is towards more diversification of what they produce. But if the standards for biological soil amendments are viewed in these sectors as an insurmountable barrier, it will limit the potential for any increases in diversification by bringing animals back onto farms that also raise produce.

Standards directed to domesticated and wild animals

The Draft EIS misses many impacts that should be assessed for a preference for animal confinement that results from the standards on animal grazing in produce fields and animal contact with agricultural water. The Draft EIS largely dismisses concerns about concentrating food animals in confinement by pointing to EPA Clean Water Act rules. But the EPA's system for regulating animal confinements has been documented by entities like the Government Accountability Office and others to be inadequate, to the extent that EPA does not even have an accurate inventory of how many of these facilities exist.

For management decisions based on the need to exclude wild animals from production areas, we urge FDA to include more consideration of the environmental and biodiversity impacts revealed during the debate over the creation of a national Leafy Greens Marketing Agreement, including findings by a survey by the Resource Conservation District of Monterey County.

Socioeconomic impacts

We are concerned that the Draft EIS minimizes the impact of management decisions to stop growing covered crops based on the final produce standards. There are several ways this impact has been minimized throughout the document.

One, as discussed earlier, is the assumption that it is easy for farms to shift their crop mix or economically feasible to do so. This is a false assumption for many sectors of agriculture and regions of the country and FDA should do much more to evaluate this impact.

Another is the statement that lost production of covered produce could be replaced by imports, without assessing impacts in terms of fuel use, practices used in exporting countries, and potential safety risks from imported produce. Simply shifting to imported produce is not the same in terms of environmental impact, nor is it an acceptable outcome for many other socioeconomic reasons, including the economic vitality of rural communities around the United States.

We are also concerned about the calculations used to justify the section on low-income populations affected by the produce standards, which seem to incorrectly discount the possibility that covered produce farms might be low-income. Relying on a median value that is higher than the national poverty line does not mean that there are not low-income farms. Those falling under the median could well fall under the poverty line level. Additionally, using household income neglects the fact that farms are small businesses with significant costs and that many small farms operate at a net loss, with household income from off-farm jobs essentially subsidizing the farm operation. The USDA's Agricultural Resource Management Survey results show that in 2013, there were 57,000 low-sales specialty crop farms with gross cash income of $37,600 and cash expenses of $42,600, which means these farms have net negative returns. If they show positive household income it is because of off-farm income. This is an inappropriate way to assume that costs of new regulations will be absorbed.

Data sources

We are concerned about the assumption made in several portions of the Draft EIS that because the majority of covered produce is being produced under some kind of marketing agreement or order, that there will be limited impact from new produce standards. While marketing agreements and orders cover large percentages of volume of some crops, primarily from larger operations, they may not cover large percentages of farms growing them. Relying on coverage by the provisions of marketing orders or agreements for specific

crops does not excuse the FDA from assessing impacts on smaller operations.

We are also curious if FDA consulted the USDA's National Organic Program for any statistics on farm size, volume of crops produced or income and costs for certified organic operations, so that the impacts of produce safety regulations could be considered with data more appropriate for that sector.

We appreciate the opportunity to comment on this important evaluation of impacts and hope that in the development of the final rule, the agency will exercise appropriate flexibility in the manner in which it treats small, diversified and organic farms.

Sincerely,

Wenonah Hauter
Executive Director

PUBLIC SUBMISSION

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Environmental Impact Statement (EIS) for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Comment On: FDA-2014-N-2244-0007
Draft Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Notice for Public Meeting on Draft Environmental Impact Statement

Document: FDA-2014-N-2244-DRAFT-0361
Comment from Janeth Hernandez , NA

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General Comment

I believe that all of the standards being set are appropriate for the optimal goal of prevention. The only thing that brings a concern are the qualifications for farms that are covered with this proposed rule. In the proposed rule there is a section about the cumulative impact that indicate the farms covered are based on how much money they make within the 3 years prior. As proposed by FDA, an average annual monetary value of produce sold during the previous 3-year period of more than $25,000 (on a rolling basis) (proposed 112.4); (2) an average annual monetary value of food sold during the previous 3-year period of more than $50,000 (on a rolling basis); (3) an average annual monetary value of food sold during the previous 3-year period of more than $100,000 (on a rolling basis); and (4) an average annual monetary value of covered produce sold during the previous 3-year period of more than $25,000 (on a rolling basis). I believe that all of this effort is relevant. However, I believe that the proposed rule leaves out smaller businesses that dont make as much money. Smaller farms still need all of the same resources to keep the public safe. Smaller farms still have consumers they need to keep safe but they can only do it when all of these services are offered. I believe that leaving smaller companies out will ultimately defeat the purpose of the act because if someone were to consumer a food purchased from a smaller farm and get sick we aren't preventing the issue at that level. I understand that perhaps the amount of profit they make may not equal those of major farmers, however, these business still sell

food and still have customers they have to protect.

National Sustainable Agriculture Coalition

March 13, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20582

Docket No. FDA-2014-N-2244
RIN 0910-AG35

Submitted electronically via http://www.regulations.gov

Re: Comments on the Draft Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

On behalf of the represented member organizations[1] of the National Sustainable Agriculture Coalition (NSAC), I submit the following comments on the Draft Environmental Impact Statement (EIS) for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.

NSAC's work on the EIS process occurs through a subcommittee of NSAC members. NSAC partners Mindy Goldstein, Jennifer Lamb, Michael McClain, Vivian Wang, and Katherine Lee at the Turner Environmental Law Clinic at Emory University School of Law contributed significantly to these comments.

NSAC looks forward to continuing to work with the FDA to ensure that the FSMA regulations and their implementation are successful and supportive of sustainable agriculture and food systems.

Sincerely,

Sophia Kruszewski

Sophia Kruszewski, Policy Specialist
National Sustainable Agriculture Coalition

[1] Agriculture and Land Based Training Association, Alternative Energy Resources Organization, California Certified Organic Farmers, California FarmLink, C.A.S.A. del Llano (Communities Assuring a Sustainable Agriculture), Catholic Rural Life, Center for Rural Affairs, Clagett Farm/Chesapeake Bay Foundation, Community Alliance with Family Farmers, Dakota Rural Action, Delta Land and Community, Ecological Farming Association, Farmer-Veteran Coalition, Fay-Penn Economic Development Council, Flats Mentor Farm, Florida Organic Growers, Grassworks, Hmong National Development, Illinois Stewardship Alliance, Institute for Agriculture and Trade Policy, Iowa Natural Heritage Foundation, Izaak Walton League of America, Kansas Rural Center, Kerr Center for Sustainable Agriculture, Land Stewardship Project, Michael Fields Agricultural Institute, Michigan Integrated Farm and Food Systems, Michigan Organic Food and Farm Alliance, Midwest Organic and Sustainable Education Service, National Center for Appropriate Technology, Nebraska Sustainable Agriculture Society, Northeast Organic Dairy Producers Alliance, Northern Plains Sustainable Agriculture Society, Northwest Center for Alternatives to Pesticides, Ohio Ecological Food and Farm Association, Organic Farming Research Foundation, Rural Advancement Foundation International – USA, Union of Concerned Scientists Food and Environment Program, Virginia Association for Biological Farming, Wild Farm Alliance.

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Comments

on

FDA Produce Rule DEIS

Submitted by

National Sustainable Agriculture Coalition

Docket No. FDA-2014-N-2244

RIN 0910-AG35

March 13, 2015

INTRODUCTION

The National Sustainable Agriculture Coalition (NSAC) welcomes the opportunity to submit these comments on the Draft Environmental Impact Statement (DEIS)[1] for the Food and Drug Administration's (FDA) proposed rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Rule).[2]

NSAC is an alliance of grassroots organizations from across the country that advocates for federal policy reform to advance the sustainability of agriculture, food systems, natural resources, and rural communities. NSAC member organizations are leaders in the sustainable agriculture and food systems sector, and they have worked with farmers and communities to pioneer practices, systems, and supply chains that support the multiple goals of sustainable agricultural systems. These organizations are invested in the development of a Produce Rule that both reduces the risks of foodborne illness and supports sustainable farm and food systems.

We appreciate FDA's engagement with the public throughout the rulemaking and National Environmental Policy Act (NEPA) process. As FDA is aware, NSAC has been an active participant. Specifically, on November 15, 2013, we submitted comments on the scope of the Produce Rule EIS (Initial Scoping Comments)[3] and comments on the proposed Produce Rule (Initial Rulemaking Comments).[4] On April 18, 2014, we submitted supplemental scoping comments on the Produce Rule EIS (Supplemental Scoping Comments).[5] On December 15, 2014, we submitted comments on FDA's Supplemental Proposed Produce Rule (Supplemental Rulemaking Comments).[6] We also provided oral testimony at the DIES Listening Session (attached as an appendix) on February 10, 2015. All of these comments are incorporated here by reference.

We believe the Produce Rule DEIS represents an important shift in FDA's thinking, recognizing the inextricable link between farming and the environment. We greatly appreciate FDA's efforts to undertake this assessment, though we have concerns with the sufficiency of the DEIS as currently written, which we describe in detail below. Despite the short timeline under which FDA must finalize the Produce Rule, it is our fervent hope that the comments FDA receives to the docket will result in an improved final EIS, and will truly inform the final Produce Rule standards. The NEPA

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[1] Draft Environmental Impact Statement for the Proposed Rule: Standards for Growing, Harvesting, Packing, and
[2] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Fed. Reg. 3,504 (proposed Jan. 16, 2013) (to be codified at 21 C.F.R. pts. 16, 112) (Produce Rule); Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, Supplemental Notice for Proposed Rulemaking, 79 Fed. Reg. 188 (proposed Sept. 29, 2014) (to be codified at 21 C.F.R 112) (Supplemental Produce Rule). The docket number for the Produce Rule is FDA-2011-N-0921 and the Regulatory Information Number (RIN) is 0910-AG35.

[3] NSAC, *Scoping Notice Comments on FDA Produce Rule*, submitted in Docket No. FDA-2011-N-0921, RIN 0910-AG35, on Nov. 15, 2013 (Initial Scoping Comments).

[4] NSAC, *Comments on the Proposed Rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, submitted in Docket No. FDA-2011-N-0921, RIN 0910-AG35, on Nov. 15, 2013 (Initial Rulemaking Comments).

[5] NSAC, *Supplemental Scoping Notice Comments on FDA Produce Rule*, submitted in Docket No. FDA-2011-N-0921, RIN 0910-AG35, on Apr. 18, 2014 (Supplemental Scoping Comments).

[6] NSAC, *Comments on the Supplemental Proposed Rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, submitted in Docket No. FDA-2011-N-0921, RIN 0910-AG35, on Dec. 15, 2014 (Supplemental Rulemaking Comments).

process plays a crucial role in informed agency decision-making. As the adage goes, "an ounce of prevention is worth a pound of cure." Not only does NEPA require a robust, genuine analysis of impacts and alternatives at the outset, but also FSMA's prevention-oriented approach surely supports taking the time necessary to ensure the EIS satisfies NEPA's mandate.

NEPA'S MANDATES

Under NEPA, an agency must prepare an Environmental Impact Statement (EIS) for any major federal action likely to significantly affect the quality of the human environment.[7] In its EIS, the agency must take a "hard look" at the environmental impacts.[8] This includes an analysis of reasonably foreseeable impacts to natural resources – such as water, land, and wildlife – as well as impacts to human health and communities.[9] Further, under NEPA, the agency must consider alternative courses of action it could undertake to avoid or mitigate such impacts.[10]

As stated by the Supreme Court, "[t]he NEPA EIS requirement serves two purposes. First, it ensures that the agency, in reaching its decision, will have available, and will carefully consider, detailed information concerning significant environmental impacts. Second, it guarantees that the relevant information will be made available to the larger audience that may also play a role in both the decision-making process and the implementation of that decision."[11] To satisfy these dual goals, FDA must set forth in the DEIS an in-depth analysis of the Produce Rule's impact on the environment and on farms and communities, particularly small- and mid-sized farms that face a disproportionately large burden to come into compliance with the new rules.

Unfortunately, the DEIS falls short of NEPA's mandate. In Chapters 1 and 2, FDA claims the DEIS analyzes the environmental impacts of several key provisions of the Produce Rule, including: (1) Subpart A, defining which farmers should be obligated to comply with the Rule; (2) Subpart E, establishing a standard for the quality of water used to irrigate produce; (3) Subpart F, determining how biological soil amendments may be applied to produce fields; and (4) Subpart I, adopting measures to reduce food safety risk from animal intrusion into produce fields.[12] In Chapters 4 and 5, however, FDA fails to adequately conduct the analysis it promised. Instead of taking a "hard look," FDA significantly underestimates – and at times, overlooks entirely – the direct, indirect, and

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[7] 42 U.S.C. § 4332(2)(C)(i).

[8] *See* 40 C.F.R. § 1502.16, (adopted by FDA at 21 C.F.R. § 25.42(a)(1)); Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 348 (1989) (NEPA "establishes 'action-forcing' procedures that require agencies to take a 'hard look' at environmental consequences."); Sierra Club v. Marsh, 976 F.2d 763, 767 (1st Cir. 1992) ("those effects that are likely or foreseeable need to be discussed"); Ctr. for Biological Diversity v. U.S. Dep't of Interior, 623 F.3d 633, 646 (9th Cir. 2010) (holding the agency violated its duties under NEPA when it failed to take a hard look at the environmental consequences of a proposed land exchange).

[9] Sierra Club v. Marsh, 976 F.2d 763, 767 (1st Cir. 1992) ("those effects that are likely or foreseeable need to be discussed").

[10] 42 U.S.C. § 4332(2)(E), 40 C.F.R. § 1502.1

[11] U.S. Dep't. of Transp. v. Pub. Citizen, 541 U.S. 752, 768 (2004) (internal citations omitted); *see also* Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 349 (1989) ("Simply by focusing the agency's attention on the environmental consequences of a proposed project, NEPA ensures the important effects will not be overlooked or underestimated only to be discovered after resources have been committed or the die otherwise cast … Publication of an EIS, both in draft and final form, also … provides a springboard for public comment").

[12] 79 Fed. Reg. 188 at 58436 (Subpart A), 58441 (Subpart E), 58457 (Subpart F), and 58463 (Subpart I); DEIS at ES-8 to ES-13.

cumulative impacts to water, air, soil, biological and ecological resources, and human health caused by the Produce Rule.

Specifically, the DEIS fails to satisfy NEPA by:

- Failing to consider certain reasonable alternatives to the Produce Rule provisions and certain actions FDA could take to mitigate the Rule's environmental impacts. We set forth a more detailed explanation of this in Part I of these comments.

- Ignoring certain impacts of the Produce Rule altogether by applying an improper test for determining the significance of an environmental impact, segmenting the analysis of the Rule's impacts on individual resources, failing to consider the cumulative impacts of the Rule, and ignoring impacts to certain groups of people and resources. We set forth a more detailed explanation of this in Part II of these comments.

- Failing to take a "hard look" at certain impacts of the Produce Rule by improperly assuming that compliance with other laws or speculative management decisions by farmers will mitigate environmental harm. We set forth a more detailed explanation of this in Part III of these comments.

By ignoring or underestimating the impacts of the Produce Rule, the DEIS fails to fully ensure informed agency decision-making and promote effective public participation. As a result, FDA may adopt the Produce Rule as proposed – committing valuable resources and causing irreversible environmental impacts – before its effects are properly evaluated. At that time, it will be too late to change course.

Accordingly, NSAC respectfully requests that FDA make significant changes to the final EIS to ensure that the EIS takes the requisite "hard look" at the direct, indirect, and cumulative impacts of the Produce Rule; alternatives to the Produce Rule; and measures that FDA can take to mitigate its impacts. We look forward to continuing to work with FDA on these important revisions.

I. THE DEIS FALLS FAR SHORT OF NEPA'S REQUIREMENTS BY FAILING TO CONSIDER CERTAIN REASONABLE ALTERNATIVES TO PRODUCE RULE PROVISIONS AND ACTIONS FDA CAN UNDERTAKE TO MITIGATE ENVIRONMENTAL IMPACTS.

NEPA requires an agency to consider in its EIS all reasonable alternatives to its proposed action, including the "no-action" alternative and a range of action alternatives.[13] This analysis is important; indeed, the meaningful analysis of alternatives is the heart of the EIS.[14] Because of its importance, a cursory listing of hypothetical and speculative alternatives is insufficient. In fact, courts have repeatedly held that an agency must analyze mitigation alternatives with sufficient detail and analytical support to ensure that environmental consequences have been fairly and fully evaluated.[15]

[13] 40 C.F.R. § 1502.14 (adopted by FDA at 21 C.F.R. § 25.10(a)).
[14] *Id.* ("This section is the heart of the environmental impact statement.").
[15] *Methow Valley Citizens Council*, at 351 (1989) ("One important ingredient of an EIS is the discussion of steps that can be taken to mitigate adverse environmental consequences"); Okanogan Highlands Alliance v. Williams, 236 F.3d 468, 473

In the DEIS, FDA's alternatives and mitigation analyses fall short of NEPA's mandate in three critical ways. First, FDA fails to consider reasonable alternatives put forth by NSAC and other commenters during the public comment periods. Second, FDA's discussion of alternatives to the proposed agricultural water provision of the Produce Rule (Subpart E) fails to meaningfully consider the environmental impacts of an alternative provision that includes drip-irrigated root crops. Third, FDA fails to consider reasonable mitigation measures that it could undertake to reduce the environmental impact of the Produce Rule. This section treats each of these issues in turn.

A. The DEIS Fails to Consider Reasonable Alternatives Set Forth in NSAC's Scoping and Rulemaking Comments.

In the DEIS, FDA fails to consider several reasonable alternatives raised by NSAC and other commenters to reduce the environmental impact of the Produce Rule.[16] When public comments call the agency's attention to a reasonable alternative to a proposed action, the agency must analyze the environmental impacts of that alternative in its EIS.[17]

FDA should have analyzed the environmental impacts of developing a microbial water quality standard for agricultural water as opposed to adopting EPA's recreational water standard in the Produce Rule. NSAC and other commenters have repeatedly requested that FDA take the time to develop an appropriate microbial water standard for agricultural water instead of adopting EPA's ill-fitting recreational water standard.[18] Taking this approach is more consistent with FSMA's mandate to develop an appropriately flexible and risk- and science-based standard for agricultural water.[19] Moreover, developing such a standard significantly reduces the likelihood that the Produce Rule will have negative impacts on the environment because: (1) a flexible, region-specific standard that is

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(9th Cir. 2000) (explaining that "a "mere listing" of mitigating measures, without supporting analytical data . . . is inadequate" under NEPA). Further, mitigation measures must not be hypothetical or speculative. NEPA Law and Litig. § 8:57 (2014) (citing Ohio Valley Envtl. Coal. v. Aracoma Coal Co., 556 F.3d 177 (4th Cir. 2009)).

[16] *See generally* NSAC, *Rulemaking Comments* (Nov. 15, 2013); NSAC *Supplemental Rulemaking Comments* (Dec. 15, 2014); National Association of State Departments of Agriculture (NASDA), *National Association of State Departments of Agriculture Comments on Proposed Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (posted online Dec. 22, 2014); United Fresh, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption - Supplemental Notice of Proposed Rulemaking* (Dec. 15, 2014); Organic Trade Association, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (Dec. 15, 2014).

[17] *See* Dubois v. U.S. Dep't of Agric., 102 F. 3d 1273, 1291 (1st Cir. 1996) ("In respect to alternatives, an agency must on its own initiative study all alternatives that appear reasonable and appropriate for study at the time, and must also look into other significant alternatives that are called to its attention by other agencies, or by the public during the comment period afforded for that purpose," *quoting* Seacoast Anti-Pollution League v. Nuclear Reg. Comm., 598 F. 2d 1221, 1230 (1st Cir. 1979)).

[18] NSAC, *Rulemaking Comments* at 66 (Nov. 15, 2013); NSAC, *Supplemental Rulemaking Comments* at 28-29 (Dec. 15, 2014); NSAC, *Produce Rule Comments* at 66 (Nov. 15, 2013); *NSAC Supplemental Produce Rule Comments* at 28-29 (Dec. 15, 2014); National Association of State Departments of Agriculture (NASDA), *National Association of State Departments of Agriculture Comments on Proposed Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* at 10-11 (posted online Dec. 22, 2014) (calling for research to develop a water standard for growing produce); United Fresh, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption - Supplemental Notice of Proposed Rulemaking* at 5 (Dec. 15, 2014) (recommending that water testing provisions reside in guidance); Organic Trade Association, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* at 3-4 (Dec. 15, 2014) (expressing that the water standard should be issued in guidance if the scientific evidence behind the standard is inconclusive).

[19] *See* NSAC, *Rulemaking Comments* at 64-66.

developed for agricultural water is less likely to be over-inclusive, thus affecting fewer farmers and allowing those farmers that are affected to avoid more extreme or expensive management decisions to achieve compliance; and (2) farmers will be able to consider their local environment in determining the best manner to keep agricultural water safe.[20] As a result, farmers will be less likely to pursue environmentally harmful measures, such as irrigating with groundwater or chemically treating their water source.[21] Further, this standard is also likely to have fewer impacts for human health and safety, as fewer agricultural workers will be exposed to harmful chemicals.[22] Because compliance with this standard would likely be less expensive, it also allows more farmers to continue to provide consumers with economically priced, healthy food choices.[23] In its DEIS, FDA should have analyzed the environmental impacts associated with adopting a standard designed by FDA specifically for agricultural water.

FDA should have analyzed the environmental impacts of developing a manure standard that appropriately accounts for application of biological soil amendments that fall between fresh manure and composted material, such as the application of aged manures.[24] NSAC strongly supports FDA's decision to move forward with a research agenda to establish a risk- and science-based standard for manure that considers the source and type of manure, the method of application, climatic conditions, type of commodity, and soil characteristics.[25] However, in the DEIS, FDA fails to consider developing a more flexible manure standard that appropriately accounts for the risks created by passive composting methods, such as aged manure or agricultural teas.[26] Creating a clear regulatory framework to allow for application of passive composting products alleviates some of the pressure on farmers to store or dispose of manure.[27] Thus, this option serves to mitigate some of the environmental impacts to water, soil, biological and ecological resources, waste disposal, and air likely to result from on-site manure storage.[28] In its DEIS, FDA should have analyzed the environmental impacts associated with developing a flexible manure standard that appropriately addresses passive composting practices.

FDA should have analyzed the impacts of codifying language to promote co-management and actively guard against habitat destruction. NSAC suggested in its comments certain proactive provisions to encourage co-management and to protect against habitat destruction.[29] In its DEIS, FDA should have analyzed the environmental impacts associated with these alternative provisions.[30]

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[20] *Id.*
[21] DEIS at 4-23 and 4-24.
[22] *Id.* at 4-35.
[23] *See* Part II.D.2 to 4.
[24] NSAC, *Supplemental Rulemaking Comments* at 35.
[25] 79 Fed. Reg. 58460.
[26] *See* DEIS at 4-40, 4-61.
[27] *Id.* at 4-44.
[28] *Id.* at 4-40 to 4-53.
[29] NSAC, *Supplemental Rulemaking Comments* at 40-41.
[30] As discussed in more detail in Part II.D.1., FDA assumes that its proposed language in § 112.84 is sufficient to prevent the destruction of habitat (and, presumably, the language proposed by NSAC is therefore not needed). *See* DEIS at 4-73, 4-74. However, § 112.84, as currently proposed, may not go far enough. The proposed provision simply *does not authorize or require* covered farms to take actions that would harm endangered species or destroy animal habitat. *See* DEIS at ES-

Failure to address in the DEIS those primary alternatives suggested through public comment directly undermines one of the critical goals of NEPA: allowing the public to play a role in the consideration and implementation of a major federal action.[31] NSAC's genuine and continued participation throughout the comment process further supports the consideration of its proposed alternatives.[32] As demonstrated above, each of the alternatives proposed by NSAC serves to mitigate the environmental impacts of FDA's Produce Rule. FDA's failure to assess these alternatives renders the DEIS inadequate.

B. The DEIS Fails to Take a Hard Look at the Impacts of an Alternative Agricultural Water Standard that Includes Drip-Irrigated Root Crops.

NSAC has repeatedly expressed its support for a water standard that excludes drip-irrigated root crops.[33] However, FDA fails to make clear in its proposed Produce Rule or Supplemental Rule that it will actually exclude drip-irrigated root crops from compliance with the water standard. Such confusion is perpetuated in the DEIS.

In the DEIS, FDA conducts its proposed alternatives analysis for the water standard exclusive of root crops.[34] FDA then notes that the environmental impacts of including root crops in the water standard would have "similar but slightly greater" effects.[35] Such a brief statement is inadequate; it fails to meaningfully analyze the considerable local and regional effects of sweeping drip-irrigated root crop production under the standard.[36] An appropriate analysis would instead look closely at the direct, indirect, and cumulative impacts caused by farmers changing irrigation water sources or increasing chemical treatment of agricultural water to comply with the water standard.[37] To the extent that the final Rule includes drip-irrigated root crops in the water standard (a result NSAC strongly discourages), the DEIS provides an inadequate assessment of the Rule's environmental impact.

C. The DEIS Fails to Consider Mitigation Measures It Could Undertake to Reduce the Environmental Impact of the Produce Rule.

NSAC commends FDA for its inclusion of a mechanism to account for microbial die-off before harvest as a means to mitigate the environmental impact of the water standard and provide flexibility to farmers faced with an otherwise inappropriate water quality standard.[38] However, FDA's analysis

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11. But, *not requiring* certain actions is not the same thing as *expressly prohibiting* them. And, the environmental impacts associate with both versions of the provision should have been analyzed in the DEIS.

[31] *See* Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 349 (1989) ("Publication of an EIS, both in draft and final form. . . provides a springboard for public comment").

[32] *See* Dubois v. U.S. Dep't of Agric., 102 F. 3d 1273, note 21 (1st Cir. 1996) (in deciding whether an agency has adequately studied all reasonable alternatives, a reviewing court may consider the extent and sincerity of the public's participation).

[33] NSAC, *Supplemental Rulemaking Comments* at 33.

[34] DEIS at 4-40.

[35] *Id.*

[36] *See* Part II.A.

[37] *See* DEIS at 4-243, 4-24.

[38] *See id.* at 4-37 to 4-38.

of mitigation alternatives still falls short for the water standard (and other provisions of the Rule) by relying solely on mitigation activities that can be undertaken by farmers, rather than actions of FDA itself.[39] Because FDA does not control the actions of farmers (nor has it tried to influence or encourage such actions through incentives or other requirements),[40] these actions are speculative at best. NEPA prohibits agencies from relying upon such speculative mitigation measures.[41] Further, focusing entirely on farmer management decisions impermissibly shifts the agency's burden to mitigate the impacts of its actions onto affected farmers. Instead, FDA must provide a reasoned discussion, supported by analytical data, of mitigation measures within its control.[42]

II. THE DEIS FAILS TO SATISFY NEPA BY IGNORING CERTAIN IMPACTS ALTOGETHER.

In the DEIS, FDA ignores certain impacts altogether by: (1) adopting a narrower test for significance than the test clearly required by its own regulations; (2) segmenting the Rule into smaller separate actions and treating the environmental impacts of those actions on each resource separately; (3) failing to place the Rule in its proper context of past, present, and reasonably foreseeable future actions; and (4) excluding impacts to particular groups and resources entirely from its analysis. This section addresses each of these inadequacies in turn.

A. The DEIS Adopts an Incorrect and Limited Test for "Significant Impacts."

NEPA requires agencies to prepare a "detailed statement . . . on the environmental impacts" of all "major federal actions *significantly* affecting the quality of the human environment."[43] The required content of an EIS is therefore determined by what impacts are termed as "significant." FDA regulations establish an exhaustive two-pronged test for identifying those significant impacts, which requires the agency to consider both the context of the action and the intensity of its effects.[44] Under the context prong, the agency must consider local and regional effects, and short- and long-term effects.[45] In assessing intensity, the test provides – among other factors – that the agency must consider effects that exist even if the agency believes that on balance those effects will be beneficial, effects that are highly uncertain or unknown, and individually insignificant effects that may have a cumulative impact.[46]

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[39] *See, e.g., id.* at 4-25, 4-26, 4-33, 4-36. For a specific enumeration of some of these management decisions, *see* Part III.B.

[40] *See* Part I.A.

[41] *See* NEPA Law and Litig. § 8:57 (2014) (citing Ohio Valley Envtl. Coal. v. Aracoma Coal Co., 556 F.3d 177 (4th Cir. 2009)) ("mitigation measures cannot be hypothetical or speculative").

[42] Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 351 (1989) ("One important ingredient of an EIS is the discussion of steps that can be taken to mitigate adverse environmental consequences"); Okanogan Highlands Alliance v. Williams, 236 F.3d 468, 473 (9th Cir. 2000) (explaining that "a "mere listing" of mitigating measures, without supporting analytical data . . . is inadequate" under NEPA). The failure of FDA to take a hard look at actions it might undertake to mitigate environmental impacts is even more egregious given the suggestions from NSAC and other commenters of viable mitigation options, like those discussed above in Part I.A above.

[43] 42 U.S.C. § 4332(2)(C)(i) (emphasis added).

[44] 40 C.F.R. § 1508.27 (adopted by FDA at 21 C.F.R. § 25.5(a)(19)).

[45] *Id.*

[46] *Id.* at § 1508.27(b).

Deviating sharply from its own regulations, FDA constructs an alternate test for significance that more narrowly defines the impacts that must be considered.[47] Specifically, FDA defines "significant impacts" as *only those* that are "readily apparent; the overall impacts may be the result of a deliberate or essential shift in management practices, which may cause an overall substantial beneficial or adverse consequence."[48] The DEIS goes on to find "no significant impacts" where "there would be minimal, moderate, or no measurable changes to the environment or resource component investigated," or where impacts could be "mitigated to avoid permanent impacts to the resource."[49] By creating this new, stricter standard for "significance," FDA overlooks many environmental impacts that should have been considered in the DEIS.

1. The DEIS Ignores Certain Impacts from Subpart E: Agricultural Water Standards.

FDA's NEPA regulations require consideration of "both short- and long- term effects."[50] In its analysis for Subpart E, FDA acknowledges that the agricultural water standards could cause farmers to use chemical treatments to bring water into compliance with the Rule.[51] However, FDA states that the increased use of chemical treatments – which can form toxic byproducts – will have no significant impact because "the effects may be reversible and are not permanent."[52] This analysis impermissibly ignores the potentially significant short-term impacts associated with the increased use of chemical water treatments.

FDA's NEPA regulations further require that the agency consider effects that are both beneficial and adverse.[53] FDA conflates these requirements when it wrongly concludes that there will be no impacts to agricultural worker health caused from increased exposure to chemicals used to treat agricultural water. According to FDA, this is so because the Produce Rule will result in a net benefit to public health through enhanced food safety.[54] We find it hard to believe, and quite concerning, that FDA would claim that a net benefit in public health could somehow cancel out the very real health hazards that farm workers face. FDA must separately acknowledge impacts to worker health and propose measures the agency may undertake to mitigate these impacts.[55]

2. The DEIS Ignores Certain Impacts from Subpart F: Biological Soil Amendments.

As noted above, FDA regulations require consideration of "both short- and long- term effects."[56] In its analysis for Subpart F, FDA states that although the biological soil amendment (BSA) standards

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[47] DEIS at 4-3, 11-8, and 11-9.
[48] *Id.* at 4-3.
[49] *Id.* at 4-3 to 4-4. FDA uses this standard for water resources and biological and ecological resources. For air quality and greenhouse gases, FDA says that an impact will not be significant if it can be "adequately mitigated using existing practices."
[50] 40 C.F.R. § 1508.27(a) (adopted by FDA at 21 C.F.R. § 25.5(a)(19)).
[51] DEIS at 4-18, 4-21, 4-37, 4-39.
[52] *Id.* at 4-39.
[53] 40 C.F.R. § 1508.27(b)(1) (adopted by FDA at 21 C.F.R. § 25.5(a)(19)).
[54] DEIS at 4-35.
[55] Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 351 (1989).
[56] 40 C.F.R. § 1508.27(a) (adopted by FDA at 21 C.F.R. § 25.5(a)(19)).

may cause farmers to switch to chemical fertilizers, the resulting impacts to soil health are not significant because they are reversible.[57] This analysis improperly ignores the potentially significant short-term soil health impacts, and the long-term impacts that degraded soil has on other biological and aquatic resources, that could result from the increased use of chemical fertilizers.

Additionally, NEPA requires consideration of potentially significant effects not only nationally, but also at the local and regional levels.[58] However, in its analysis for Subpart F, FDA improperly dismisses potentially significant impacts of the biological soil amendment standard on the basis that these impacts would not occur on a national scale. For example, FDA states that many impacts from Subpart F will be insignificant because of the relatively small percentage of farmers who use BSAs nationally.[59] This analysis does not account for the fact that BSA users may be regionally or locally concentrated, and the standard could cause a significant local or regional impact. FDA also states that although a required application interval for BSAs of animal origin would lead to increased storage and transportation of manure, the resulting increase in emissions of particulate matter, greenhouse gases (GHGs), and ozone precursors are not significant because they would be localized.[60] This analysis again directly contravenes FDA's obligation to consider local and regional impacts, and thus impermissibly ignores the potentially significant impacts that could result from the increased storage and transportation of manure.

And, as with the agricultural water standard discussed above, FDA misapplies the consideration of both beneficial and adverse effects in its assessment of public health impacts from the BSA standard.[61] FDA acknowledges that workers will face increased chemical exposure in application of chemical inputs.[62] Yet the DEIS weighs the impacts on these workers against the public health benefits of the Rule.[63] As a result, FDA fails to consider that the effects to workers may be significant, even if there is an overall health benefit from pathogen reduction. Again, FDA must separately acknowledge the risks posed to agricultural workers and propose activities the agency can undertake to mitigate these impacts. Failure to do so treats farm worker health as somehow separate from public health, and sacrifices the health of farm workers to further the good of the consuming public. This would be an unconscionable result.

3. The DEIS Ignores Certain Impacts from Subpart I: Standards Directed to Domesticated and Wild Animals.

FDA's NEPA regulations require consideration of "both short- and long- term effects."[64] However, in its analysis for Subpart I, FDA dismisses short-term or reversible impacts as insignificant in two places. First, FDA states that although requiring a waiting period for harvesting after the intrusion of domesticated animals on crop areas would result in more concentrated livestock (and therefore soil compaction and more concentrated waste runoff), the impacts are not significant because they

[57] DEIS at 4-57.
[58] 40 C.F.R. § 1508.27(a) (adopted by FDA at 21 C.F.R. § 25.5(a)(19)).
[59] DEIS at 4-45 (water), 4-55 (air quality), 4-56 (human health and safety), 4-57 (water).
[60] *Id.* at 4-54.
[61] *Id.* at 4-56.
[62] *Id.*
[63] *Id.*
[64] 40 C.F.R. 1508.27(a) (adopted by FDA at 21 C.F.R. § 25.5(a)(19)).

are short-term.[65] Second, FDA states that although requiring farmers to wait an appropriate length of time to harvest produce after evidence of wild animal intrusion may result in an increased use of herbicides, rodenticides, and other chemicals to exclude wildlife, the impacts are not significant because the chemical components last a short-term after application.[66] FDA's analysis in these two instances impermissibly ignores the potentially significant short-term impacts to water, soils, and biological and ecological resources that could result from the standards under Subpart I.

FDA also fails to consider regional and local effects of the proposed provisions regarding grazing in produce fields.[67] FDA correctly acknowledges that the exclusion of animals from grazing in produce fields may require farmers to restrict animals to other pastures or to confine animals in feedlots,[68] echoing a concern raised in NSAC's scoping comments.[69] However, because the standard would apply to "only a small amount of produce," FDA does not consider the effect of increased manure accumulation and disposal to be significant.[70] Similarly, FDA recognizes that increased animal confinement may result in increased particulate matter emissions from manure storage and farms transitioning to chemical pesticides, but dismisses the impact because of the relatively small number of farms likely to be affected.[71] In reaching these conclusions, FDA abdicates its responsibility to consider the regional and local impacts of its Rule.

B. The DEIS Impermissibly Segments the Rule.

When evaluating the potential environmental impacts of a proposed action, NEPA prohibits an agency from labeling a particular action as insignificant "by breaking it down into small component parts."[72] As numerous courts have found, this "prevent[s] agencies from dividing one project into multiple individual actions each of which individually has an insignificant environmental impact, but which collectively have a substantial impact."[73] To that end, in a single EIS, reviewing agencies must consider all "connected actions" – including those actions that are "interdependent parts of a larger action and depend on the larger action for their justification."[74]

FDA considers the impacts to water, soil, biological and ecological resources, and air separately in the DEIS for standards directed to agricultural water (Subpart E), standards directed to biological soil amendments of animal origin (Subpart F), and standards directed to domesticated and wild animals (Subpart I) of the Produce Rule. Although FDA makes an effort to unify its segmented analyses at the end of Chapter 4 of the DEIS,[75] this section merely restates the conclusions from

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[65] DEIS at 4-67.
[66] *Id.* at 4-75.
[67] *Id.* at 4-70 to 4-71.
[68] *Id.* at 4-70.
[69] NSAC, *Initial Scoping Comments*, at 26-28.
[70] DEIS at 4-70
[71] *Id.* at 4-71.
[72] 40 C.F.R. § 1508.27(b)(7) (adopted by FDA at 21 C.F.R. § 25.10 5(a)(19)).
[73] *See e.g.,* Del. Riverkeeper Network v. FERC, 753 F.3d 1304, 1314 (D.C. Cir. 2014) (internal quotation marks omitted) (holding that FERC violated NEPA by impermissibly segmenting its environmental review).
[74] 40 C.F.R. § 1508.25(a)(1)(3) (adopted by FDA at 21 C.F.R. § 25.10(a)).
[75] DEIS at 4-88 to 4-95.

Sections 4.2 through 4.6 of the DEIS sequentially, without providing an assessment of the entire, collective impact all the various provisions of the Produce Rule have on each individual resource.

This structure of the DEIS – segmenting the Rule into singular provisions and analyzing impacts on individual resources separately for each provision – leads FDA to underestimate the Rule's complete environmental impacts on water, soil, biological and ecological resources, and air quality.

Water. FDA claims that there will be no adverse impacts to water related to Subpart F's standards for BSAs or Subpart I's standards for wildlife intrusion.[76] Further, though FDA recognizes that the agricultural water standards in Subpart E could cause significant impacts related to groundwater drawdown, FDA claims that impacts to groundwater quality and water availability will not be significant, despite recognizing that Subpart E could cause increased pesticide use.[77] However, FDA fails to adequately consider the impacts to water of the entire Rule, considered in the aggregate. FDA must take a hard look at the overall impacts to water quality that could result from the combination of increased pesticide use, animal confinement or other exclusionary measures, and decreased water availability.

Soil. FDA does not consider at once all the effects of each subpart of the Produce Rule that could lead to a decrease in soil health.[78] In its separate analyses for Subparts E and F, FDA acknowledges that both subparts could cause short-term impacts to soils, primarily from increased chemical fertilizer and pesticide use.[79] Similarly, FDA finds that Subpart I could cause short-term impacts to soils because of increased soil compaction and nutrient run-off.[80] However, at the end of Chapter 4 of the DEIS, where FDA purports to consider the impacts of all these subparts together, FDA only considers the impacts to soils from Subpart F.[81] FDA must consider the aggregate impacts to soils that could result from all of the Rule's subparts, particularly the combined impact of increased soil compaction, nutrient run-off, chemical fertilizers, and pesticides.

Biological and Ecological Resources. FDA does not consider the aggregate effects of each subpart of the Produce Rule that could cause a degradation of ecosystems or wildlife diversity.[82] In its analysis of the agricultural water standards under Subpart E, FDA finds that, although the standards could increase chemical water treatment and degrade surface and groundwater quality, the standards will not significantly impact biological and ecological resources.[83] For Subpart F, FDA finds that the standards for BSAs could cause minimal but not significant impacts from increased chemical fertilizer use, peat mining, and runoff from manure storage.[84] Finally, for Subpart I, FDA states that there could be minimal impacts from increased herbicides, rodenticides, and pesticide use, land

[76] *Id.* at 4-74 (wildlife intrusion) and 4-89 (BSAs).
[77] *Id.* at 4-81, 4-89.
[78] *Id.* at 4-90.
[79] *Id.* at 4-57
[80] *Id.* at 4-70.
[81] *Id.* at 4-90.
[82] *Id.* at 4-89 to 4-90.
[83] *Id.* at 4-37 to 4-38.
[84] *Id.* at 4-46 to 4-48.

clearing, hunting and trapping, and the disruption of wildlife corridors.[85] However, in its purported analysis of the cumulative impacts of these subparts, FDA merely restates its conclusions from each individual subpart, and does not consider that there could be a significant impact to biological and ecological resources when all the Produce Rule standards are taken together.[86] In particular, FDA must consider the aggregate impacts to biological and ecological resources that could result from increased chemical use, land clearing, hunting and trapping, peat mining, and nutrient runoff caused by the Produce Rule.

Air Quality. FDA does not consider the aggregate impacts from each subpart of the Produce Rule that could lead to local, regional, or national increases in GHGs, particulate matter, and ozone precursor emissions.[87] FDA admits that there could be small, localized increases in emissions from each of Subparts E, F, and I.[88] However, in its analysis for all these subparts together, FDA merely states that "[t]here are minimal adverse impacts … associated with air quality and greenhouse gases."[89] Through this conclusory statement, FDA fails to consider that the small, localized increases in air emissions from each subpart could, in the aggregate, lead to significant impacts. FDA must assess these impacts in the DEIS.

C. The DEIS Fails to Include a Meaningful Cumulative Impacts Analysis.

When evaluating the potential environmental impacts of a proposed action, NEPA requires agencies to consider "[c]umulative actions, which when viewed with other proposed actions have cumulatively significant impacts."[90] This is because some actions may cause significant environmental impacts only when viewed in conjunction with all other related actions.[91]

Thus, to satisfy NEPA's mandates, agencies are required to take a hard look at "the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time."[92]

Chapter 5 of the DEIS contains FDA's cumulative impacts analysis for the Produce Rule.[93] While citing to the correct regulations,[94] the DEIS nevertheless inadequately considers a number of significant cumulative environmental effects. Specifically, FDA unreasonably limits the foreseeable future impacts it considers in the DEIS, fails to consider impacts of the Rule taken together with impacts from other regulations promulgated under FSMA, impermissibly relies on the speculative

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[85] *Id.* at 4-75 to 4-76.
[86] *Id.* at 4-89 to 4-90.
[87] *Id.* at 4-91.
[88] *Id.* at 4-33 (Subpart E), 4-53 (Subpart F), 4-71 (Subpart I).
[89] *Id.* at 4-91.
[90] 40 C.F.R. 1508.25(a)(2) (adopted by FDA at 21 C.F.R. § 25.5(a)(18)).
[91] 40 C.F.R. § 1508.27(b)(7) (adopted by FDA at 21 C.F.R. § 25.5(a)(19)).
[92] 40 C.F.R. § 1508.7 (adopted by FDA at 21 C.F.R. § 25.5(a)(3)).
[93] DEIS at 5-1 to 5-30.
[94] *Id.* at 5-1.

management decisions of farmers to mitigate cumulative impacts, and fails to consider local and regional cumulative effects of the Produce Rule over time.

1. The DEIS artificially limits the reasonably foreseeable future impacts of the Rule.

In the DEIS, FDA artificially limits the "reasonably foreseeable future" impacts it considers to those impacts arising within the six-year period following promulgation of the Produce Rule.[95] While there is no regulatory standard for the length of time an agency must consider in its assessment of cumulative impacts, its decision must be reasonable – i.e. the agency must consider the "relevant factors" and demonstrate a "rational connection between the facts found and the choice made."[96]

In the DEIS, FDA made no showing that the reasonably foreseeable future impacts of the Produce Rule should be limited to this six-year window. Indeed, the only rationalization provided for this limited time-frame is that it reflects the date by which all farms must come into compliance with the Produce Rule's requirements.[97] But that date marks the *beginning* of when the complete impacts from the Produce Rule can be assessed, not the end. The Produce Rule's impacts will extend far into the future, and FDA must consider those impacts in its cumulative impact analysis.

2. The DEIS fails to consider the impacts of the Rule in conjunction with the impacts of the other FSMA rules.

In the DEIS, FDA dismisses from consideration any cumulative impacts from the suite of FSMA rules by simply noting that each of the other five FSMA rules has been categorically excluded from the NEPA process.[98] This reasoning, of course, circumvents the very purpose of a cumulative impact analysis, which is to ensure that even those actions that seem insignificant in isolation do not have significant environmental impacts when viewed in the context of other related actions.[99] In fact, NSAC has repeatedly expressed concern that, in light of the combined costs of compliance with the Produce Rule and Preventive Controls Rule, small farms may close and significant environmental impacts – including impacts to public health, farmers, and communities – may result.[100] FDA's failure to meaningfully consider the combined effect of the suite of FSMA regulations renders the cumulative impacts analysis in the DEIS inadequate.

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[95] *Id.*

[96] Selkirk Conservation Alliance v. Forsgren, 336 F. 3d 944, 962 (9th Cir. 2003) (recognizing that the scope of the EIS is a "delicate choice" and should be entrusted to the agency, but the agency must have "considered the relevant factors and articulated a rational connection between the facts found and the choice made").

[97] *See* DEIS at 5-1 and Table 2.1-8.

[98] These regulations include the Intentional Adulteration Rule, the Sanitary Transportation of Human and Animal Food Rule, the Preventative Controls for Human Food Rule, the Foreign Supplier Verification Programs for Importers of Food for Humans and Animals Rule, and the Third Part Accreditation Rule. DEIS at 5-3 to 5-4.

[99] Hanly v. Kleindienst, 471 F.2d 823, 831 (2d Cir. 1972) ("it must be recognized that even a slight increase in adverse conditions that form an existing environmental milieu may sometimes threaten harm that is significant. One more factory polluting air and water in an area zoned for industrial use may represent the straw that breaks the back of the environmental camel.").

[100] *See* NSAC, *Supplemental Rulemaking Comments* at 26; NSAC, *Comments on the Supplemental Proposed Rule for Current Good Manufacturing Practice and Hazard Analysis and Risk Based Preventive Controls for Human Food* at 26 (Dec. 15, 2014) .

3. The DEIS impermissibly relies on management decisions of farmers to mitigate the cumulative impacts of the Rule.

FDA also dismisses the cumulative impacts of the Produce Rule when examined with past, present, and reasonably foreseeable future agency actions by reasoning that farmers will make certain management decisions to mitigate the impacts. The problem with relying on the speculative and voluntary actions of farmers to mitigate impacts is more fully discussed in Part I.C of these comments.[101] Within its cumulative impacts analysis, FDA impermissibly relies on speculative farmers' decisions to mitigate the impacts of the Produce Rule with regard to water, soil, and biological and ecological resources.

Water. With respect to the agricultural water standards under Subpart E, FDA states that the ability of farmers to apply the microbial die-off rate will mitigate the impacts that could occur from a switch to chemical treatment.[102] In addition, FDA states that farmer participation in voluntary marketing programs, including Good Agricultural Practices (GAPs) certification, will further mitigate the impacts of the Rule.[103] With respect to Subpart F, FDA states that although a switch to chemical fertilizers in response to an imposed application interval for BSAs of animal origin may contaminate surface and groundwater, there is no significant cumulative environmental impact because those effects may be mitigated by farmers adopting best management practices.[104] FDA provides no data to support its wide-ranging assumptions. NEPA requires FDA to consider the impacts that may arise if farmers choose to chemically treat water, choose not to participate in voluntary marketing programs, or choose not to adopt certain nutrient management practices.

Soil. FDA states that, although a switch to chemical fertilizers in response to an imposed application interval for BSAs of animal origin will have detrimental effects on soil health, there is no significant cumulative environmental impact because these effects can be mitigated through green manuring, no-till practice, and the use of cover crops.[105] While we certainly support such mitigation measures, we do not share the agency's optimism regarding their adoption. As discussed in more detail below in Part III.B.3, the current rates of adoption of these practices are actually quite low, which casts serious doubts on the agency's assumption. FDA provides no data to support its assumption that farmers will adopt such practices,[106] and NEPA requires FDA to consider the impacts if farmers choose not to them.

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[101] *See* Part I.C.

[102] DEIS at 5-18.

[103] *Id.* FDA further acknowledges that it does not know the number of farmers participating in such programs relative to the total number of farms that would be covered by the Produce Rule, making its reliance on voluntary programs even more suspect.

[104] *Id.* at 5-19.

[105] *Id.* at 5-21.

[106] Notably, as discussed in Part III.A.6, many of these activities are promoted by the Natural Resource Conservation Service (NRCS). However, FDA provides no explanation that NRCS will likely have the resources available to facilitate adoption of these activities by farmers or that farmers will, in fact, choose to adopt them.

Biological and Ecological Resources. FDA states that grower participation in voluntary marketing programs will limit the adverse effects to biological and ecological resources caused by an increase in chemical treatment of agricultural water.[107] FDA also assumes that because §112.84 of the Produce Rule does not require farmers to destroy animal habitat or clear farm borders, farmers will never to choose to take these measures.[108] NEPA requires FDA to consider the impacts that will arise if farmers make other reasonable management decisions.

4. The DEIS fails to consider future local and regional effects of the Rule.

As discussed in more detail in Part II.A of these comments, NEPA requires consideration of potentially significant effects not only nationally, but also at the local and regional levels. Throughout the DEIS, FDA improperly limits its definition of significant impacts to those that occur at a national scale.[109] In its cumulative impacts analysis, FDA commits this legal error in at least three places:

(1) FDA states that the Rule will cause no significant cumulative effects on biological or ecological resources because these measures cannot be measured on a national scale.[110] However, significant impacts can occur at a local or regional scale, and these impacts must be assessed.
(2) FDA states that because the Rule does not impact air quality at a national level, the cumulative effects of the Rule on air quality are not significant.[111] This analysis impermissibly ignores potentially significant local or regional impacts on air quality.
(3) FDA states that there is no significant cumulative impact to water quality as a result of the Rule's standards under Subpart F because only 2.3 percent of farms nationally could switch from untreated BSAs to chemical fertilizers.[112] We are not convinced that this statistic is accurate at the national level, and furthermore, this analysis does not account for the fact that BSA users may be regionally or locally concentrated, resulting in a significant local or regional impact due to the regulation.

D. The DEIS Fails to Consider Particular Resources and Affected Groups.

Beyond the environmental impacts that FDA has overlooked by applying an incorrect test for significance, segmenting the Rule, and ignoring cumulative impacts, the DEIS also altogether ignores the following significant environmental impacts of the Produce Rule.

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[107] DEIS at 5-19.
[108] *Id.* at 5-20. For a fuller discussion of the problems with this assumption, see Part II.D.1.
[109] *See* Part II.A.
[110] DEIS at 5-20.
[111] *Id.* at 5-22.
[112] *Id.* at 5-19. The 2.3 percent referenced in the DEIS is cited to the Regulatory Impact Analysis of the Proposed Produce Rule, which in turn cites to the Washington State NASS website, and not any particular study or report.

1. The DEIS fails to consider impacts to endangered species.

Proposed § 112.84 states: "Nothing in this regulation authorizes the "taking" of threatened or endangered species as that term is defined by the Endangered Species Act … This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages."[113] FDA misinterprets the effect of this provision and, throughout the DEIS, FDA assumes that the language "does not authorize or require" has the same effect as "prohibits." Thus, FDA concludes that the provision will entirely prevent farmers from impacting endangered species. This is simply incorrect. The Rule does not prohibit such action, and FDA must consider the impacts to endangered species that may arise from farmers taking measures to exclude animals.[114]

2. The DEIS often ignores impacts on the continued operation of small farms.

The Produce Rule will have a disproportionate impact on small and very small farms. Indeed, in the DEIS, FDA acknowledges that "small and very small farms may not be able to afford the added cost burden of complying" with the Rule's provisions.[115] FDA avoids assessing the impact of the closure of these small and very small farms by both (1) claiming that data are unavailable to make such an assessment, and (2) assuming that small farms will not choose to close. NEPA, however, requires more.

FDA states that the data are unavailable or too uncertain to make any conclusions about the impacts that the closure of small and very small farms will have on the environment, food access, socioeconomic outcomes, and human health.[116] But when data are unavailable, NEPA does not allow an agency to simply ignore impacts. Rather, NEPA requires FDA to use theoretical approaches or research methods generally accepted in the scientific community to estimate these impacts.[117]

FDA assumes that, despite the high costs of compliance, small and very small farms will make management decisions to stay in operation and continue growing covered produce.[118] But, as discussed more fully below in Section III, FDA must consider all reasonable management decisions farmers may take in response to the Produce Rule, including the decision to cease or drastically change operations.[119]

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[113] *Id.* at 4-7.
[114] For a more detailed discussion, *see* Part III.A.3.
[115] DEIS at ES-28 to ES-29, 4-92. The burden of compliance with the Rule is likely greater than FDA acknowledges because FDA failed to consider additional costs arising from (1) the significant record keeping requirements imposed by Subpart O of the Produce Rule, and (2) the additional requirements that could be imposed from buyers/third-party auditors in response to the Produce Rule.
[116] *Id.* at ES-28 to ES-29, 4-93.
[117] 40 C.F.R. § 1502.22(b) (adopted by FDA at 21 C.F.R. § 25.10(a)).
[118] *See* Part III.B.1; DEIS at 4-28.
[119] *See* Part III.B.1.

3. The DEIS ignores impacts to prospective farmers.

In addition to affecting the decision of farmers to remain in operation, the high cost of compliance with the Produce Rule may also deter prospective farmers from deciding to grow covered produce.[120] This is especially disconcerting given the aging farm population and the decline of younger entrants into the market.[121] But nowhere in the DEIS does FDA assess impacts to these prospective farmers. NEPA requires such an assessment, even if "the possible effects on the human environment are highly uncertain or involve unique or unknown risks."[122]

4. The DEIS ignores impacts to vulnerable populations resulting from reduced access to fresh produce, including minorities.

If the costs of compliance with the Produce Rule lead some small farms to close (as discussed in Part II.D.2 above), or slows the entry of new farmers into the market (as discussed in Part II.D.3 above), small, rural, or underserved communities may have decreased access to fresh produce. Moreover, for farms that remain in operation, the increased costs of compliance may be passed on to consumers.[123] Small, rural, and underserved communities may not be able to afford increased food prices.

NEPA mandates that FDA assess *all* the impacts of decreased access to fresh produce on these communities, even if the impacts are difficult to predict. FDA's decision to only evaluate (1) the limited impact on these populations as a result of Subpart F's requirements,[124] and (2) the Produce Rule's socioeconomic impacts on farm operators and farm workers, is unacceptable, especially where the health of older or otherwise sensitive populations is disproportionately at risk.

Moreover, while FDA acknowledges that Indian tribes may be disproportionately affected by the Rule,[125] FDA ignores impacts to other minority groups. For example, in considering the increased use of pesticides, FDA concludes that "there are no impacts anticipated on human health as a result of secondary or worker exposure to pesticides. Therefore, there are also no anticipated significant impacts to minority groups."[126] By generalizing impacts from minority agricultural workers and

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[120] DEIS at 4-91. Table 4-7 summarizes the costs of complying with the Produce Rule for existing farmers. While FDA does not provide data specifically addressing the cost of compliance for new entrants, it is reasonable to extend estimations from Table 4-7 to that group. *See also* NSAC *Supplemental Rulemaking Comment* at 19, 25.

[121] Jim Mitchell, et. al., *The Aging Farm Population and Rural Aging Research,* 13 J. of Agromedicine 95, (2008) ("from 1954 to 1997 the number of younger persons choosing farming as an occupation decreased from 15 to 8%, while the proportion of farmers aged 55 and over increased from 37 to 61%."); *Ag 101: Demographics*, ENVIRONMENTAL PROTECTION AGENCY, *available at* http://www.epa.gov/agriculture/ag101/demographics.html ("The average age of a principal operator of a farm has increased from 54 years old in 1997 to 57 years old in 2007. (USDA, 2007 Census of Agriculture). The percentage of principle farm operators 65 years or older has increased almost 10 percent since 1969").

[122] 40 C.F.R. §1508.27 (adopted by FDA at 21 C.F.R. §25.5(a)(19)).

[123] DEIS at 5-24.

[124] DEIS at 4-58.

[125] *Id.* at 4-24.

[126] *Id.* at 4-35.

applying them wholesale to minority groups, FDA ignores potentially significant impacts to these sensitive populations.

III. THE DEIS FAILS TO SATISFY NEPA BY SIGNIFICANTLY UNDERESTIMATING ENVIRONMENTAL IMPACTS.

In the DEIS, FDA significantly underestimates certain environmental impacts, by making a series of misplaced assumptions about the mitigating effects of (1) compliance with other environmental laws and voluntary programs, and (2) the management decisions of farmers. Individually, each of these assumptions erodes significant components of FDA's environmental analysis. Cumulatively, these assumptions lead FDA to conclude that a regulation of tremendous scope – designed to alter the way produce is grown, packed, and held in this country – will have only minor environmental impacts.[127] To satisfy its obligations under NEPA, FDA must revisit and correct each of these mistaken assumptions.

A. The DEIS Improperly Assumes that Compliance with a Law, Permit, or Voluntary Program will Result in Minimal or No Environmental Impact.

When an agency presumes that compliance with another agency's requirements means that the environmental effects of a proposed action are insignificant, the agency impermissibly abdicates its NEPA obligations.[128] In particular, courts have rejected agencies' reliance on the Endangered Species Act (ESA) to avoid consideration of environmental impacts to endangered species.[129]

Throughout the DEIS, FDA improperly assumes that the compliance with the Clean Water Act (CWA), the Fungicide, Insecticide, and Rodenticide Act (FIFRA), the ESA, and state regulatory programs will result in minimal or no environmental impact from the Produce Rule's key provisions. FDA repeats this mistake in a more egregious manner by likewise assuming that compliance with voluntary food safety certification programs and voluntary marketing agreements will also result in minimal or no environmental impact. Below we provide examples of these misplaced assumptions.

1. The DEIS improperly relies on the CWA and complimentary state nutrient management plans to underestimate impacts.

FDA's misplaced reliance on the CWA and state nutrient management plans causes it to underestimate impacts to:

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[127] FDA ultimately concludes that the only potentially significant environmental impact of the Produce Rule is that it may result in further depletion of groundwater resources. *Id.* at 4-38.

[128] Calvert Cliffs' Coordinating Comm., Inc. v. Atomic Energy Comm'n, 449 F.2d 1109, 1122-23 (D.C. Cir. 1971) (stating that if an agency could rely entirely on the environmental judgments of other agencies, NEPA would "wither away in disuse", and that such a tactic is in fundamental conflict with NEPA's purpose). *See also* Southern Oregon Citizens Against Toxic Sprays, Inc. v. Clark, 720 F.2d 1475, 1480 (9th Cir.1983) ("[o]ne agency cannot rely on another's examination of environmental effects under NEPA").

[129] *See, e.g.,* Makua v. Rumsfeld, 163 F. Supp. 2d 1202, 1218 (D. Ha. 2001) (holding that agency's reliance on assurances that its action would not "jeopardize the continued existence of a species" under the ESA is not equivalent to a finding that there would be "no significant impact" on a given species); *see also* 40 C.F.R. § 1508.27(b)(9) (indicating that any action that adversely affects endangered or threatened species or their critical habitats, as defined by the ESA, should likely be considered in an EIS).

- Water resources (for example, DEIS at 4-45, 4-57, 4-89)
- Biological and ecological resources (for example, DEIS at 4-11, 4-47, 4-68, 4-69)
- Soil (for example, DEIS at 4-49)
- Waste generation, disposal, and resource use (for example, DEIS at 4-50, 4-52, 4-84)

First, throughout the DEIS, FDA grossly overestimates the number of farms that are required to obtain National Pollutant Discharge Elimination System (NPDES) discharge permits under the CWA.[130] For farms, NPDES permits are the exception, and most agricultural operations are specifically exempted from needing these permits to operate.[131] Only when a farm is operating a concentrated animal feeding operation (CAFO) is that farm required to apply for a NPDES permit.[132] And even then, many farmers are able to simply avoid the permitting process.[133]

For the dredge and fill permit program, CWA regulations also make explicit exceptions for ongoing farming operations and irrigation activities.[134] In the DEIS, FDA ignores these exceptions, and again overestimates the number of farms that will be regulated by the CWA through this permitting program.

Second, the DEIS incorrectly assumes that, if a farm has a NPDES permit or dredge and fill permit (and, perhaps, even if it does not), adherence to permit requirements will prevent any significant environmental impact.[135] Here, FDA fundamentally misunderstands the nature of CWA permitting programs. By design, NPDES permits *allow* for the discharge of pollutants into water.[136] A dredge and fill permit likewise recognizes that the activities undertaken will result in impacts to water resources.[137] Therefore, FDA cannot rely on permits that fundamentally allow for pollution as a means to mitigate environmental harm.

Finally, for those farms that are not obligated to apply for a NPDES permit, FDA states that compliance with state nutrient management plans will also mitigate the Rule's environmental impact.[138] This assumption is simply inaccurate. Agricultural runoff is the leading cause of pollution in our waterways[139] – despite the CWA or the implementation of state nutrient management plans.

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130 DEIS at 4-45, 4-52. *See also id.* at 4-50 ("Many farms and/or CAFOs that generate animal waste are required to comply with NPDES or other permits.").
131 *See* 33 U.S.C. § 1362 (6) and (14).
132 *See id.* Moreover, when a farm applies for NPDES permit for the operation of a CAFO, that permit has no bearing upon manure management in produce production activities. Instead, it only restricts discharges from the CAFO itself.
133 Only CAFOs that discharge must apply for a permit. *See* U.S. EPA, Concentrated Animal Feeding Operations Final Rulemaking—Factsheet, (2008), *available at:* http://www.epa.gov/npdes/pubs/cafo_final_rule2008_fs.pdf.
134 40 C.F.R. § 232.3(c)(1).
135 *See, e.g.*, DEIS at 4-45, 4-47, and 4-52.
136 *See* 33 U.S.C. § 1342(a)(1).
137 *Id.* at § 1344.
138 DEIS at 4-45.
139 National Water Quality Inventory: Report to Congress (2004) at 12. *See also* Jan G. Laitos & Heidi Ruckreigle, *The Clean Water Act and the Challenges of Agricultural Pollution,* 37 Vt. L. Rev. 1033, 1037 (2013) ("agricultural pollution accounts for approximately half of the country's water pollution").

Thus, FDA's reliance on the CWA to mitigate the impacts to water from increased agricultural chemical runoff,[140] unintentional releases of stored manure,[141] moving livestock to new land for grazing,[142] and adding fencing to exclude domesticated animals from produce fields[143] is entirely misplaced. The CWA simply does not apply to most farming activities; and in any event, the CWA and state nutrient management plans do not prohibit environmental harm. FDA must meaningfully consider the significant environmental impacts that may arise from the Produce Rule, even while farmers adhere to the limited mandates of the CWA.

2. The DEIS improperly relies on FIFRA to underestimate impacts.[144]

FDA's misplaced reliance on FIFRA causes it to underestimate impacts to:

- Water resources (for example, DEIS at 4-21, 4-28, 4-30, 4-45, 4-68, 4-69, 4-74, 4-76)
- Biological and ecological resources (for example, DEIS at 4-30, 4-76, 4-77, 4-89, 4-90)
- Human health (for example, DEIS at 4-35, 4-77)

FIFRA regulates the labeling, sale, and distribution of pesticide and herbicide products.[145] These pesticides and herbicides, by design, are intended to kill or disrupt living organisms. Consequently, their intentional release into the environment poses significant risks to water, biological and ecological resources, and human health. FIFRA does not completely eliminate these risks.[146] Indeed, because FIFRA does not establish a permitting system for pesticide use and instead regulates solely through registration and labeling, risks associated with the release of pesticides in a particular geographic location at a particular time are not even evaluated.[147] As such, FDA cannot discharge its duty under NEPA to take a hard look at the impacts of pesticide use by merely stating that pesticides are regulated under FIFRA. Agricultural chemical runoff is a serious cause of environmental harm to water resources and the biological and ecological resources that depend upon water, notwithstanding FIFRA's requirements.

In addition, the DEIS impermissibly assumes that no environmental impact will be caused by the chemical treatment of water. FDA posits that because EPA may someday approve a label for the chemical treatment of agricultural water under FIFRA, this prospective process will protect the water from harm.[148] Such reliance on a future treatment product (that hasn't even been proposed to let alone approved by EPA) is impermissible – NEPA requires FDA to take a hard look at the reasonably foreseeable impacts of increased chemical treatment of agricultural water, and FDA cannot assume that speculative future actions of EPA will entirely mitigate these impacts.[149]

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[140] DEIS at 4-43
[141] *See id.* at 4-45, 4-52.
[142] *Id.* at 4-67.
[143] *Id.* at 4-69.
[144] *Id.* at 4-37.
[145] *See* ENVTL. PROT. AGENCY. Fungicide, Insecticide, and Rodenticide Act, http://www.epa.gov/agriculture/lfra.html.
[146] FIFRA's standard of "unreasonable harm" does not preclude environmental impacts due to increased use of pesticides. 7 U.S.C. § 136a (c)(5).
[147] Instead of a permitting program, EPA's regulation of pesticides is accomplished through labeling restrictions. *See* 40 C.F.R. § 156.10.
[148] DEIS at 4-21.
[149] NEPA Law and Litig. § 8:57 (2014) (citing Ohio Valley Envtl. Coal. v. Aracoma Coal Co., 556 F.3d 177 (4th Cir. 2009)) ("mitigation measures cannot be hypothetical or speculative").

3. The DEIS improperly relies on the ESA to underestimate impacts.[150]

FDA claims that the "proposed requirements [of the Produce Rule] do not propose any activity that may result in impacts to threatened or endangered species."[151] FDA reaches this conclusion because proposed § 112.84, discussed in more detail in Part II.D.1, does not *require* the taking of endangered species. Of course, *not requiring* something is not the same as *prohibiting* it. And thus, impacts to endangered species could certainly occur even while a farmer adheres to the Produce Rule's mandates.

FDA avoids consideration of these impacts, however, because it assumes the U.S. Fish and Wildlife Service (USFWS) will protect endangered species under the ESA.[152] By this logic, no EIS (other than an EIS prepared by the USFWS) would ever address impacts to endangered species. That, of course, is not what NEPA requires. Rather, both FDA and Council on Environmental Quality regulations require the agency to take a hard look at impacts to endangered species.[153] FDA may not rely on the ESA to entirely avoid NEPA's mandate.

4. The DEIS improperly relies on state and county permits for hunting, trapping, or poisoning of wildlife to underestimate impacts.

FDA correctly recognizes that farmers may resort to increased hunting, trapping, or poisoning of wildlife to prevent animal intrusion into produce fields.[154] Instead of taking a hard look at the impacts to the environment from these management decisions, FDA reasons that because such activities will be regulated at the state or local level there will be no environmental harm.[155] However, increased hunting, trapping, or poisoning of wildlife in response to the Rule, even if legally permissible and regulated by states or counties, will still negatively impact biological and ecological resources. NEPA prohibits FDA from ignoring these impacts.

Moreover, FDA consistently places impacts from fencing, trapping, hunting, and poisoning in the same category. However, each of these practices can have substantially different impacts on wildlife. As such, FDA should have considered these measures separately to assess their relative impacts.

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150 DEIS at 4-6 to 4-8.

151 *Id.* at 4-6, 4-74.

152 DEIS at 4-7 to 4-8. ("To the extent a grower of produce takes an action that may impact a threatened or endangered species, such action would be subject to the independent oversight and authority of the USFWS … we would consider the regulatory oversight of the USFWS for such an action to sufficiently mitigate the potential for any significant environmental impact under NEPA.")

153 *See* 40 C.F.R. § 1508.27(b)(9) (in evaluating the severity of an impact, an agency should consider "the degree to which the action may adversely affect an endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973") (adopted by FDA at 21 C.F.R. § 25.10(a)).

154 DEIS at 4-75.

155 *Id.*

5. The DEIS improperly relies on voluntary marketing programs or Good Agricultural Practices to underestimate impacts.

FDA's misplaced reliance on voluntary marketing programs and GAPs causes it to underestimate impacts to:[156]

- Water resources (for example, DEIS at 4-21)
- Waste generation, disposal, and resource use (for example, DEIS at 4-50)

FDA hypothesizes that impacts to water from the Produce Rule will be minimized because some voluntary marketing agreements maintain more restrictive standards than the Rule, and thus many farmers would not have to change their current practices to come into compliance with the Rule's requirements.[157] This hypothesis, however, does not account for the fact that these programs are voluntary and often commodity-specific. Consequently, (1) some farmers have chosen not to opt into the programs, (2) some farmers grow produce not covered by these programs, and (3) some farmers may choose to opt out of these programs in the future. For all of these farmers, the severity of impacts caused by the Produce Rule's water standards will not be minimized, and FDA must take a hard look at these impacts.

In addition, the DEIS wrongly implies that no environmental impact will be caused by farmers switching to treated BSAs, so long as they adhere to industry standards or GAPs.[158] However, compliance with industry standards or GAPs is voluntary. Moreover, industry standards and GAPs do not necessarily have a bearing on environmental health, as neither aim to improve environmental outcomes. As such, reliance on industry standards or GAPs to entirely mitigate environmental impacts is misplaced, and FDA must take a hard look at impacts that may be caused by farmers switching to treated BSAs, or synthetic ones.

6. The DEIS improperly relies on Natural Resources Conservation Service (NRCS) conservation programs to underestimate impacts.

FDA's misplaced reliance on NRCS conservation programs causes it to underestimate impacts to:

- Water resources (for example, DEIS at 4-45)

While NRCS programs are established and available at the county level throughout the country, participation in these programs is voluntary and undertaken in accordance with a farmer's own initiative.[159] Thus, for farmers who opt not to use NRCS programs, these programs cannot mitigate the environmental impacts of their management decisions. Moreover, and perhaps more importantly, NRCS programs primarily focus on activities beyond food safety on produce farms.[160]

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[156] *Id.* at 4-51.
[157] *Id.*
[158] *Id.*
[159] *See* U.S. DEP'T OF AGRIC., Natural Resources Conservation Service, *available at* http://www.nrcs.usda.gov/.
[160] DEIS at 4-11, 5-5 ("NRCS's natural resources conservation programs help people reduce soil erosion, enhance water supplies, improve water quality, increase wildlife habitat, and reduce damages caused by floods and other natural disasters.").

Individual NRCS offices simply may not have the resources or expertise to mitigate the specific environmental impacts caused by the Produce Rule. As a result, FDA's reliance on NRCS programs to entirely mitigate the environmental impacts of its Rule is again misplaced.

In addition, FDA wrongly relies upon farmers adopting technologies traditionally promoted through technical assistance of the NRCS to mitigate impacts from its Rule. For example, throughout the DEIS, FDA claims farmers will practice strip tillage, use green manuring, and implement riparian buffers.[161] Not only does this impermissibly shift FDA's burden to mitigate environmental impacts to farmers, but it also impermissibly relies on the expenditure of another agency's resources to mitigate the environmental impacts of the Produce Rule.[162]

B. The DEIS Fails to Consider the Environmental Impacts Arising from All Reasonably Foreseeable Management Decisions.

NEPA requires agencies to take a "hard look" at *all* reasonably foreseeable impacts when preparing an EIS.[163] And while agencies can take into account mitigation measures that may reduce these impacts, these measures may not be hypothetical, speculative, or unsupported by data.[164] Despite this mandate, in the DEIS, FDA focuses entirely on management decisions that farmers may voluntarily adopt to mitigate the environmental impacts of the Rule, while ignoring other possible management decisions that farmers may make that would increase environmental impacts.[165] FDA provides little support for its choice to conduct such a narrow review.

NEPA mandates that FDA take a broader look – the agency must consider *all reasonably foreseeable management decisions* that a farmer could make (taking into account the many factors that may affect a farmer's decision, including crop type, soil conditions, environmental conditions, and cost) to comply with the Rule, and then assess the environmental impacts that could arise from each of these decisions.[166]

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[161] *Id.* at 4-49, 4-51, 4-62.

[162] *See* Part III.A.

[163] *See* 40 C.F.R. § 1502.16, (adopted by FDA at 21 C.F.R. § 25.42(a)(1)); Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 348 (1989) (NEPA "establishes 'action-forcing' procedures that require agencies to take a 'hard look' at environmental consequences."); Sierra Club v. Marsh, 976 F.2d 763, 767 (1st Cir. 1992) ("those effects that are likely or foreseeable need to be discussed"); Ctr. for Biological Diversity v. U.S. Dep't of Interior, 623 F.3d 633, 646 (9th Cir. 2010) (holding the agency violated its duties under NEPA when it failed to take a hard look at the environmental consequences of a proposed land exchange).

[164] NEPA Law and Litig. § 10:43 (2014).

[165] In Chapters 1 and 2 of the DEIS, FDA claims that it will assess all reasonably foreseeable management decisions. But, FDA's list of management decisions is incomplete, failing to include certain decisions raised in NSAC's previous comments. In addition, the impact analysis FDA conducts in Chapter 4 does not even include all the management decisions listed in Chapters 1 and 2 of the DEIS. In effect, the FDA limits its analysis to only those management decisions that will significantly mitigate environmental impacts – notwithstanding economic considerations, ease of implementation, and practicality.

[166] DEIS at 2-12.

1. Subpart A. General Provisions.

In its analysis for Subpart A, in which FDA purports to assess the impacts related to all of the provisions of the Produce Rule together, FDA entirely fails to analyze the direct or indirect impacts of a management decision to cease farming.

Despite the fact that many provisions of this Rule will impose new and substantial administrative, financial, and operational burdens on farmers, FDA repeatedly asserts that the possibility that farmers may choose to cease farming (instead of taking on these new burdens) is both unlikely and too speculative to analyze.[167] We respectfully disagree. It is reasonably foreseeable that the burden may be too large for some farms to bear, and FDA must, at a minimum, address in its DEIS the theoretical environmental impacts that would result – including direct impacts to land and indirect socioeconomic and human health impacts (if, for example, certain at-risk populations have reduced access to fresh produce and certain farmers cannot find new employment).[168]

2. Subpart E. Agricultural Water Standard.

FDA omits reasonably foreseeable management decisions from its analysis. In its analysis of Subpart E, FDA fails to consider two reasonably foreseeable management decisions that farmers could take to comply with the agricultural water standard: the decision to close down small farms and the decision to switch to municipal water.

- FDA fails to consider the management decision, particularly of small and very small farms, to cease farming.[169] FDA does not meaningfully analyze the direct or indirect environmental impacts of those closures, stating that there are no data to suggest when such a decision would be made.[170] As discussed previously in Part II.D, it is reasonably foreseeable that farmers could elect to close down their farms instead of coming into compliance with the Rule, and thus FDA is required to analyze the direct, indirect, and cumulative environmental impacts that would result. To the extent data are unavailable, FDA must nevertheless evaluate impacts based upon theoretical approaches.[171]

- While FDA admits that the agricultural water standard could cause farmers to switch to groundwater,[172] it does not analyze the impacts from a farmer's decision to switch to

[167] *See, e.g., id.* at 4-28 to 4-29.
[168] *See* 40 C.F.R. § 1502.22(b) (adopted by FDA at 21 C.F.R. § 25.10(a)).
[169] In addition, FDA fails to adequately consider impacts related to a decision to switch from growing covered produce to raising livestock or growing non-covered produce because several comments the agency received claimed that those were not "preferred management decision[s]." DEIS at 4-28. NEPA, however, requires an agency to consider all reasonably foreseeable impacts, not just those that were identified in initial comment periods. *See* 40 C.F.R. § 1502.16, (adopted by FDA at 21 C.F.R. § 25.42(a)(1)).
[170] DEIS at 4-28 to 29.
[171] 40 C.F.R. § 1502.22(b) ("If the information relevant to reasonably foreseeable significant adverse impacts cannot be obtained because the overall costs of obtaining it are exorbitant or the means to obtain it are not know, the agency shall include within the environmental impact statement … (4) the agency's evaluation of such impacts based upon theoretical approaches or research methods generally accepted in the scientific community.") (adopted by FDA at 21 C.F.R. § 25.10(a)).
[172] DEIS at 4-30, 4-32.

municipal water. Considering that sprout growers already use municipal water to conduct agricultural activity[173] and given the scarcity of surface and groundwater supplies, it is reasonably foreseeable that some farmers could choose to switch to municipal water.[174] To comply with NEPA, FDA must consider the environmental impacts of this decision.

FDA improperly assumes farmers will take voluntary measures to mitigate the impacts of Subpart E. As established in Part I.C, FDA cannot rest its conclusions about the impacts of the Produce Rule on voluntary and speculative management decisions by farmers. Within its impacts analysis for Subpart E, FDA does so in three places:

- FDA acknowledges that Subpart E could cause farmers to increase their use of chemicals, particularly pesticides, to treat water. Pesticide pollution, of course, has serious adverse effects on water, biological and ecological resources, and human health.[175] FDA claims that these significant impacts would be "mitigated by the ability of covered farmers to choose other management decisions," including "switching water sources, switching the irrigation method to a non-contact method, or adding mechanisms to account for microbial die-off in the field and post-harvest."[176] But, FDA does not provide support for (1) its assumption that farmers will always choose one of these alternative management decisions, or (2) that these alternative decisions would mitigate the impacts from increased chemical treatment.

- While FDA is correct in its conclusion that non-contact irrigation methods result in fewer environmental impacts than other irrigation methods,[177] FDA incorrectly relies on non-contact irrigation – along with other voluntary measures by growers – to avoid a full discussion of the environmental impacts associated with Subpart E if farmers do not switch irrigation methods. Importantly, the switching of irrigation method is an option for only a limited variety of crops.[178]

- Alternative I under Subpart E (the preferred alternative) allows farmers to use microbial die-off and/or removal – instead of chemical treatment or switching water sources – to meet the proposed agricultural water standards.[179] While this added flexibility may decrease the number of farms that either use chemical treatment or decide to switch water source,[180] FDA goes too far in its conclusion that microbial die-off will "overall mitigate the potential need for or significant impacts associated with other management decisions."[181] In times of drought, farmers may not have the luxury of being able to wait the appropriate amount of time for the die-off rate. FDA fails to explain why it is not reasonably foreseeable that some farmers will still choose to chemically treat water or switch water sources. The impacts of these management decisions must be assessed.

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[173] *Id.* at ES-24.
[174] NSAC, *Supplemental Scoping Comments* at 4.
[175] DEIS at 4-21, 4-23.
[176] *Id.* at 4-23 (water), 4-36 (human health); *see also* 4-27 (discussing die-off) and 4-37 to 4-38.
[177] *Id.* at 4-26.
[178] *Id.*
[179] *Id.* at 4-18.
[180] *Id.* at 4-18, 4-23.
[181] *Id.* at 4-27, 4-37 (because farmers will have the option to use microbial die-off, there will be no significant impacts from long-term chemical treatment of water).

In assuming that farmers will always adopt certain management decisions (and by making all the other improper assumptions discussed throughout these comments), FDA fails to take a hard look at the impacts of the water provision.

3. Subpart F. Biological Soil Amendments – Untreated and Treated.

FDA's omits reasonably foreseeable management decisions from its analysis. In its analysis for Subpart F, treated BSAs, FDA fails to consider any management decision except compliance with the proposed waiting period. This is because FDA assumes that growers who are already using treated BSAs will continue to do so, as §112.56(a)(4)(i) of the Produce Rule does not impose a waiting period.[182] However, the application waiting period is only one part of the proposed treated BSA standard; the Rule also requires certain procedures regarding the use, handling, and storage of BSAs, as well as record-keeping requirements.[183] The additional administrative and procedural burdens required by the Rule could result in farmers electing to switch to chemical fertilizer, stop growing covered produce, or shut down the farm. NEPA requires FDA to analyze the environmental impacts of these reasonably foreseeable management decisions.

FDA improperly assumes that farmers will take voluntary measures to mitigate the impacts of Subpart F. As established in Part I.C, FDA cannot rest its conclusions about the impacts of the Produce Rule on voluntary and speculative management decisions by farmers. Within its impacts analysis for Subpart F, FDA does this in two places:

First, as FDA acknowledges, implementing a longer application interval under Alternatives I, III, IV, and V would require longer manure storage times and could result in increased manure runoff.[184] However, FDA finds that this would cause no significant adverse impacts to water quality or biological and ecological resources.[185] To reach this conclusion, FDA improperly relies on best management practices by farmers, claiming that farmers' implementation of these voluntary measures will significantly mitigate the potential for impacts to surface water, groundwater, and soils.[186]

Second, the use of chemical fertilizers has serious adverse effects on soils, water systems, and biological and ecological resources.[187] Subpart F of the Rule may impose restrictions on the use of BSAs of animal origin, which could cause farmers to switch to chemical fertilizers. In concluding that the resulting impacts would be insignificant, FDA partly relies on its assertion that there is a "growing trend away from chemical fertilizers to practices such as green manuring."[188] As noted throughout these comments, it is unreasonable for FDA to rely so heavily on a trend that is both voluntary and wholly outside of the agency's control.

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[182] *Id.* at 4-61 to 4-62.
[183] *Id.* at 4-61, 4-90.
[184] DEIS at 4-45.
[185] *Id.* at 4-45, 4-47 to 4-48.
[186] *Id.* at 4-49, 4-57.
[187] *Id.* at 4-47, 4-49.
[188] *Id.* at 4-57.

Although we strongly support green manure and cover crop practices, we do not agree with the agency's assumption regarding the pervasiveness of the practice. While a few farmers on the cutting edge of the soil health initiative are growing the kind of high biomass, multispecies cover crops and using the kind of minimum-till minimum-chemical methods needed to protect soil health, most vegetable producers, including many organic producers who try their best to take good care of the soil, are working their soil hard and need BSAs to maintain soil quality. Moreover, green manuring and cover crops serve different roles in a crop system: cover crops protect and feed soil biota by adding nitrogen and carbon to the soil, BSAs replenish the soil microbtioa and mineral nutrients.

The reality is that, in some parts of the country (i.e. the Corn Belt), practices like green manuring are around 2 percent of total acreage. While that figure is likely to be higher among produce growers, it is very unlikely to be above 30 - 40 percent, and may be considerably less. Vegetable production is a very intensive system, and both the soil and the farmer are often too occupied for effective cover cropping. Even when a cover crop is planted, it may not reach the size / biomass needed to ameliorate soil quality, either because it was planted too late (due to the late harvest of cash crop or a busy farmer) and/or because it had to be terminated too early (its time to plant the next cash crop, or due to weather complications).

In assuming or overemphasizing that farmers will always adopt certain management decisions (and by making all the other improper assumptions discussed throughout these comments), FDA fails to take a hard look at the impacts of the BSA provision.

4. Subpart I. Standards Directed to Domesticated and Wild Animals/Grazing – § 112.82(a).

FDA omits reasonably foreseeable management decisions from its analysis of § 112.82(a). FDA identifies several management decisions that a farmer may take to comply with the standards of §112.82(a): fencing or other measures to exclude domesticated animals, and observing an adequate waiting period after grazing and prior to harvest.[189] FDA also acknowledges that farmers may confine animals to small pasture and/or feedlots, which would result in greater accumulation of manure at times when these animals would be permitted to graze.[190] Yet FDA ignores other potential management decisions, such as the likelihood that farms with integrated crop-livestock systems would stop raising livestock and/or stop growing covered produce. This reduces the diversity of the farming operation, with attendant environmental impacts and impacts to public health and communities. However, most notably, FDA largely ignores the possibility that farmers may clear conservation buffers from field borders or riparian areas and drainages that would attract roaming livestock.[191]

To reach this conclusion, FDA relies partly on §112.84 of the Produce Rule, which states that farmers are not *required* to "take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas."[192] Because

[189] *Id.* at 4-66.
[190] *Id.* at 4-70.
[191] *Id.* at 4-68.
[192] *Id.*

farmers are not required to fence or clear-cut, FDA states that farmers will instead choose to purchase other food sources for their domestic animals or use other land for grazing.[193] But, §112.84 does not *prohibit* fencing or clear-cutting, and FDA fails to adequately explain why it is not reasonably foreseeable that some growers will choose to build new fences or use clear-cutting to exclude animals.[194] It is well documented that clearing habitat/non-crop vegetation including weeds can negatively affect bees, monarch butterflies, and birds.[195] The impact of these omitted management decisions must be assessed.

FDA improperly assumes farmers will take voluntary measures to mitigate the impacts of Subpart I - § 112.82(a). As established in Part I.C, FDA cannot rest its conclusions about the impacts of the Produce Rule on voluntary and speculative management decisions by farmers. Within its impacts analysis for §112.82(a), FDA does this in at least one place:

- To reduce the incentive for farmers to clear field borders, the DEIS implicitly assumes that farmers will purchase alternative food sources for livestock or use other land for grazing.[196] However, FDA does not provide any data to substantiate the availability of these alternatives or to support the likelihood that farmers would adopt such alternatives as opposed to clearing field or drainage borders. As such, FDA's mere listing of these speculative activities fails to discharge the agency's obligation under NEPA.

In assuming that farmers will always adopt certain management decisions (and by making all the other improper assumptions discussed throughout these comments), FDA fails to take a hard look at the impacts of the domesticated animal provision.

5. Subpart I. Standards Directed to Domesticated and Wild Animals/Animal Intrusion – § 112.83(b).

FDA omits reasonably foreseeable management decisions from its analysis of § 112.83(b). Alternative I of this Subpart (the preferred alternative) requires farmers to monitor fields for animal intrusion, evaluate whether produce can be harvested safely, and if the produce is contaminated, to forego harvesting that portion of the crop.[197] In its impacts analysis for this alternative, FDA assumes that farmers will not take measures to prevent wildlife intrusion, such as clearing farm borders or increasing use of toxic chemicals.[198] Because the only management decisions that FDA

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[193] *Id.*

[194] *Id.* at 4-72. FDA also claims that because most dual-purpose farms already have fencing in place, the construction of new fencing is unlikely. *Id.* at 4-69. However, FDA fails to provide support for this argument, and therefore this statement fails to satisfy the agency's obligations under NEPA.

[195] *See* Arlettaz, R. et al. 2012. Journal of Ornithology doi:10.1007/s10336-011-0737-7; Gillespie, M. and Â S.D. Wratten. 2012. Journal of Insect Conservation doi:10.1007/s10841-011-9390-y; Requier, F. et al. 2014. Honey bee diet in intensive farmland habitats reveals an unexpectedly high flower richness and a major role of weeds. Ecological Applications doi: 10.1890/14-1011.1; Pleasants, JM and Oberhauser KS (2013), Milkweed loss in agricultural fields because of herbicide use: effect on the monarch butterfly population. Insect Conservation and Diversity, 6:Â 135–144. doi:Â 10.1111/j.1752-4598.2012.00196.x; and Beecher, N. A., R. J. Johnson, et al. (2002). Agroecology of birds in organic and nonorganic farmland. Conservation Biology 16(6): 1620-1631.

[196] *Id.* at 4-68.

[197] *Id.* at 4-77.

[198] *Id.* at 4-77 to 78.

considers is that farmers will monitor their fields or potentially establish fences to exclude animals from produce fields, FDA concludes that there will be "no significant adverse effects … to any resource component" from §112.83(b).[199]

To reach this conclusion, FDA relies on §112.84, which states that farmers are not required to destroy animal habitat or clear farm borders.[200] However, as discussed in Part II.D, the Produce Rule does not forbid farmers from clear-cutting or destroying animal habitat, and thus FDA's conclusion that farmers will never take these measures is unreasonable. In fact, California farmers have taken this very action to comply with GAPs measures to prevent wildlife intrusion into farmers' fields.[201] In some cases, this has resulted in farmers abandoning conservation practices they had previously adopted.[202] Measures taken by farmers include the removal of tailwater recovery ponds and irrigation reservoirs, grassed waterways, filter and buffer strips, trees and shrubs.[203]

FDA is required to consider all reasonably foreseeable impacts, and therefore must assess the impacts to water, biological and ecological resources, and soils that would result if farmers chose to clear-cut or otherwise destroy animal habitat or use toxic chemicals to prevent animal intrusion. In light of past experience, ignoring the potential environmental impacts of this provision by unreasonably assuming that farmers will somehow respond differently to a mandatory rule than to a voluntary food safety program flies in the face of FDA's obligations under NEPA.

Although new §112.83(b) provides some clarity that farmers do not have to destroy animal habitat under the rules, it does not – as discussed above – forbid farmers from clear-cutting or destroying habitat, nor does it encourage farmers not to, and to instead co-manage for conservation and food safety. Thus, FDA's conclusion that farmers would never take these measures is unreasonable.

FDA improperly assumes farmers will take voluntary measures to mitigate the impacts of Subpart I - § 112.83(b). As established in Part I.C, FDA cannot rest its conclusions about the impacts of the Produce Rule on voluntary and speculative management decisions by farmers. Within its impacts analysis for §112.83 (b), FDA does this in at least one place:

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[199] *Id.* at 4-74.

[200] *Id.*

[201] *See* David M. Chron & Mary L. Bianchi, *Research Priorities for Coordinating Management of Food Safety and Water Quality*, 37 J. ENVTL. QUALITY 1411, 1412 (2008). The concern that adopting measures for food safety may undermine efforts to promote water quality led 100 food safety and water quality experts to meet to develop a research agenda to accommodate both concerns. *Id.* at 1411; *see also* Resource Conservation District of Monterey County, *Challenges to Co-Management of Food Safety and Environmental Protection: A Grower's Survey* Jul. 2009, available at: http://caff.org/wp-content/uploads/2011/09/Challenges_Grower_Survey_July2009. pdf; Wild Farm Alliance, Environmental Destruction in the Salinas Valley: 'Food Safety' Requirements to Remove Habitat Make Leafy Greens Less Safe, (2008), *available at* http://wildfarmalliance.org/resources/WFA%20FS%20EnvDestruct2.pdf; Sasha Gennet, et al., *Farm practices for food safety: an emerging threat to floodplain and riparian ecosystems,* 11 FRONTIERS IN ECOLOGY AND THE ENV'T. 236 (2013); Diana Stuart, *Coastal Ecosystems and Agricultural Land Use: New Challenges on California's Central Coast* 38 COASTAL MGMT. 1, 42-64 (2010); Diana Stuart & Sean Gillon. *Scaling Up to Address New Challenges to Conservation on U.S. Farmland*, 31 LAND USE POL'Y 223 (2013).

[202] David M. Chron & Mary L. Bianchi, *Research Priorities for Coordinating Management of Food Safety and Water Quality*, 37 J. ENVTL. QUALITY 1411, 1412 (2008).

[203] *See id.*

- FDA claims that any potential adverse impacts to wildlife resulting from the standards in §112.83(b) will be mitigated because there are co-management measures and best management practices available that allow farmers to direct wildlife away from fields while still providing adequate habitat.[204] Because these measures and practices are voluntary and fall completely outside of FDA's control, it is unreasonable and impermissibly speculative for FDA to rely upon them to mitigate impacts.[205] Moreover, as set forth in the outset of these comments, FDA did not consider the impact of codifying language that would create incentives for farmers to preserve wildlife habitat.[206] If FDA were to explicitly support such practices in the regulations, then it would be more reasonable for FDA to assume that farmers would use co-management to mitigate impacts. To the extent that FDA relies on this misplaced assumption, its discussion of environmental impact is inadequate.

In assuming that farmers will always adopt certain management decisions (and by making all the other improper assumptions discussed throughout these comments), FDA fails to take a hard look at the impacts of the wild animal provision.

CONCLUSION

NEPA requires FDA to conduct an in-depth review of the environmental impacts of the Produce Rule. Unfortunately, the DEIS fails to satisfy the requisite analysis. As set forth in more detail above, the DEIS:

- Fails to consider reasonable alternatives to the Produce Rule's provisions that were raised in public comment;
- Fails to consider activities that FDA could undertake to mitigate the environmental impacts of the Produce Rule;
- Ignores certain impacts of the Produce Rule altogether; and
- Significantly underestimates certain impacts of the Produce Rule.

These failures undermine informed agency decision-making and meaningful public participation. Consequently, NSAC respectfully requests that FDA take the time necessary to improve the DEIS so that it takes the requisite "hard look" at the direct, indirect, and cumulative impacts of the Produce Rule; alternatives to the Produce Rule; and measures FDA can take to mitigate its impacts. NSAC looks forward to continued work with FDA during the duration of this NEPA process.

[204] DEIS at 4-75.
[205] *See* Part III.B. and Part II.D.1.
[206] *See* Part I.A.

National Sustainable Agriculture Coalition

February 10, 2015

FDA Public Listening Session on the Draft Environmental Impact Statement for the Proposed Rule on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Re: NSAC Comments on the Draft Environmental Impact Statement

Thank you for this opportunity to comment on the Draft Environmental Impact State (DEIS). My name is Sophia Kruszewski and I am a Policy Specialist for the National Sustainable Agriculture Coalition (NSAC). NSAC is an alliance of over 100 grassroots organizations across the country that advocate for federal policy reform to advance the sustainability of agriculture, food systems, natural resources, and rural communities.

NSAC member organizations are leaders in the sustainable agriculture and food systems sector, and have worked with farmers and communities to pioneer practices, systems, and supply chains that support the multiple goals of sustainable agricultural systems, including access to fresh, healthy food. Many NSAC member organizations work directly with small and mid-sized sustainable and organic farmers and on-farm food processors who conduct activities within the scope of FDA's proposed rules. Many also work directly with farmers and USDA's Natural Resources Conservation Service field staff at the state and county level to enroll working farmland in conservation programs to conserve and enhance the quality of our soil, water, air, and wildlife habitat.

FSMA, and the produce rule in particular, is guaranteed to impact the agricultural landscape. The agricultural landscape is inextricably linked to the environment. Throughout the legislative and rulemaking processes, NSAC has voiced concerns that the FSMA regulations may result in unnecessary adverse environmental impacts, particularly by discouraging farmers from maintaining and adopting beneficial conservation practices on their farms.

We also sought to ensure that the agency properly consider any other adverse impacts of the rule on air, soil, water, habitat, and human health. We are very pleased that the agency recognized that these rules – and this rule in particular – could have such environmental impacts, and that it agreed to conduct a full environmental review of the Produce Rule under NEPA.

NEPA's importance in the rulemaking process is two-fold: First, it ensures that the agency will have available, and will carefully consider, information necessary to determine whether its action could have significant environmental impacts. Second, and no less important, it provides the public with an opportunity to participate and weigh in on the agency's decision-making process. And so we commend the agency for undertaking this complex task, and for providing the public with significant opportunity to weigh in on the scope, and now content, of the DEIS.

It is our fervent hope that this process is not in vain, and that – court-imposed deadlines aside – the agency will seriously consider what modifications are needed to ensure the EIS provides a robust assessment of impacts as the Produce Rule is finalized. Given the short timeline, and the haste with which the agency had to complete this DEIS, we have some concerns about its adequacy. We will be providing written comments and recommendations on the DEIS once we have fully reviewed it.

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In the meantime, I provide the following initial concerns:

First, data. There are many instances throughout the DEIS where the agency acknowledges a lack of data necessary to fully assess any impacts. We recognize that data limitations are a significant problem, a problem that has plagued numerous aspects of this rulemaking. NEPA requires the agency take a hard look at the impacts, and perform the best analysis it can, with the best available data. Thus, the agency must do a careful, thorough search for all available data. If the data are not there, the agency must make its best, most reasoned estimates of impacts. The agency cannot simply choose not to consider important impacts just because the data is hard to locate or incomplete.

Second, cumulative impacts. NEPA requires FDA to consider the cumulative impacts of the rule together with other reasonably foreseeable impacts beyond the rule itself. This should include not only a consideration of the impacts of the Produce Rule in tandem with the rest of the FSMA rules, but also a consideration of the impacts associated with farms – particularly small and very small farms – that choose to stop growing covered produce, and the associated impacts on the economy and access to fresh fruits and vegetables. Unfortunately, the DEIS makes light of the effects to farmers that will be covered by multiple rules. We have consistently urged the agency to clearly identify and articulate the extent to which farms may be subject to multiple rules, without result, and the agency's failure to meaningfully discuss this scenario in the DEIS continues this troubling trend.

Finally, we are incredibly concerned by the agency's reliance on other laws, regulations, or voluntary compliance programs to mitigate the environmental impacts of the rule. The agency cannot abdicate its duty to analyze environmental impacts under NEPA; yet the agency consistently does just that - determining that there is no need to assess water quality impacts because of the Clean Water Act, or pesticide application impacts because of FIFRA. This strikes me as overly optimistic, if not downright naïve, and it runs counter to clear legal precedent, which says the agency cannot rely on compliance with another agency's requirements in a NEPA review. This issue is particularly troublesome where the agency defers to compliance with voluntary programs like NRCS conservation programs, or USDA GAPs. Both are which are *voluntary* programs, not to mention that the latter is not geared toward environmental health.

Again, we are very pleased with the opportunity to provide feedback on the DEIS. This was a massive undertaking, and an exceedingly important one. But the fact that the DEIS did not come out until after the rule's two comment periods ended and must now be hastily completed in time for the October deadline does give us some doubt that the agency will truly consider public input at this stage in the process. We hope that the agency will take this feedback and all the comments and suggestions received on the DEIS to improve the overall analysis, and consider the impacts of the rule *before* making any final decisions about the rule itself, as NEPA requires.

On all of these issues, we will follow up with specific recommendations in our comments to the docket, and we look forward to continuing to work with the agency to ensure that the regulations and their implementation are successful in meeting public health goals, and are supportive of sustainable agriculture and food systems.

Thank you,

Sophia Kruszewski, Policy Specialist
National Sustainable Agriculture Coalition

PUBLIC SUBMISSION

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Environmental Impact Statement (EIS) for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Comment On: FDA-2014-N-2244-0007
Draft Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Notice for Public Meeting on Draft Environmental Impact Statement

Document: FDA-2014-N-2244-DRAFT-0372
Comment from Altagracia Perez, Cal State University Los Angeles

Submitter Information

Name: Altagracia Perez
Organization: Cal State University Los Angeles

General Comment

I think that these provisions are an important start to preventing food borne outbreaks, considering that recent sources of outbreaks have originated in farm settings. Setting a standard for the number of Escherichia coli colony forming units helps determine whether the water is being treated properly and if any measures have to be taken. But it is also important to consider developing new methods to detect the presence of parasitic oocysts or cysts in water. The method of water treatment is also of importance since some parasites have been able to acquire resistance to chlorination. Taking measures to prevent animals from accessing plants that are being cultivated is important but I also think that it might not be an easy measure to enforce. Considering that it will be at the farmers discretion whether they are checking this and whether they decide to use the produce if animal contact has occurred. Deciding which farms are to be included in this rule based on how much they contribute annually I feel would be a good way to decrease the number of farms that have to be inspected and spend more time evaluating them to ensure that they are following with the correct provisions. But if farms that make less than the amount indicated are not included then what rules will be set for them and will they get inspected as often? Finally I appreciate that the publics comments are being considered since we are the ones that are most affected when the produce we are receiving is not safe to consume. This also provides me with the opportunity to know that I am able to contribute to ideas when new rules are being formed regarding the food industry.

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE

March 13, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852.

Docket No. FDA-2014-N-2244

Thank you for the opportunity to submit comments on the Draft Environmental Impact Statement for the proposed rule establishing standards for the growing, harvesting, packing, and holding of produce for human consumption.

The Pennsylvania Department of Agriculture (PDA) has longstanding relationships in promoting and ensuring a safe food supply, both with FDA and with growers, packers, handlers and processors across the Commonwealth. Our Bureau of Food Safety and Laboratory Services plays a critical role in protecting Pennsylvanians and our visitors by regulating the tens of thousands of eating and drinking establishments, retail food stores, and food manufacturers/processors found across the state to ensure compliance with food safety laws. In addition to licensing and regulating, PDA offers services through Good Agricultural Practices audits on farms, commodity inspections in processing facilities, and milk inspection services across the state.

PDA believes that the Food Safety Modernization Act will offer benefits to the agriculture industry as well as to consumers. A greater focus on prevention is likely to prevent costly and damaging food safety outbreaks and recalls. We also recognize the importance of balancing food safety and prevention with other needs, including the economic viability of Pennsylvania's $75 billion agriculture industry. PDA's mission is to encourage, protect and promote agriculture and related industries throughout the Commonwealth, while providing consumer protection through inspection services that impact the health and financial security of Pennsylvania's citizens. We believe that risk management from a food safety perspective must be balanced with keeping a healthy agriculture industry and healthy environment. Food safety risks will never completely be eliminated – we must agree on an acceptable level of risk that also maintains a continued supply of healthy, nutritious produce for consumers.

PDA reiterates its previous comments from 2013 and 2014 on the produce safety rule, in four key areas: definition of covered farms, water quality standards, use of raw manure and compost, and provisions affecting domesticated and wild animals.

1. Definition of Covered Farms

The final definition of farm is one of the most critical aspects of the produce safety regulation because it touches on the rest of the proposed regulations for registered food facilities. PDA acknowledges that one definition will not fit all, but that it must fit most, and the definition must be constructed based on common sense, how businesses operate, to improve public health, and be organized in a way to facilitate high rates of compliance.

PDA appreciates FDA's efforts to improve the definition of "farm" by broadening it to include more activities, particularly those associated with raw agricultural commodities (RACs), regardless of whether the RACs originate on that farm or another. This change was an important step toward ensuring that farms are not unnecessarily regulated or regulated in a way that fails to advance public health.

PDA reiterates its previous comments regarding FDA's supplemental definition of "farm," and proposes the following revisions:

> **Farm** means an establishment ~~*under one ownership* in one general physical location~~ devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term "farm" includes establishments that, in addition to these activities:
>
> (i) **Pack or hold** raw agricultural commodities;
>
> (ii) **Pack or hold** processed food, provided that all processed food used in such activities is either consumed *within the establishment* ~~on that farm or another farm under the same ownership~~, or is processed food identified in paragraph (iii)(B)(1) of this definition; and
>
> (iii) **Manufacture/process** food, provided that:
>
> (A) All food used in such activities is consumed *within the establishment* ~~on that farm or another farm under the same ownership~~; or
>
> (B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:
>
> (1) **Drying/dehydrating** raw agricultural commodities to create a distinct commodity, and **packaging and labeling** such commodities, without additional manufacturing/processing; and
>
> (2) **Packaging and labeling,** *including repackaging and/or relabeling* raw agricultural commodities, when these activities do not involve additional manufacturing/processing.

The revisions above would resolve many of the lingering questions about the definition. PDA requests FDA clarify the packaging and labeling activity by including repackaging and relabeling because this similar practice does not increase the risk to public health and is incidental to packaging and labeling activities.

Removing reference to "under one ownership" and replacing it with the term "establishment" allows more discretion with respect to examining the context of a business operation rather than its legal construct. Fundamentally, ownership is not germane to food safety – but processes and

practices are. A business enterprise that includes a farm, produce stand, and hauling business may be organized as several individually organized entities, yet be managed by the same farm owners/managers. PDA must be able to work effectively with the regulated farms in order to establish the extent of the business and how the business's compliance should be evaluated. Furthermore, although PDA could elect to distinguish between the size and scope of a business independently, it is important that the final definition not be limited to the construct of ownership.

By referencing an "establishment" in the farm definition rather than ownership, it is also possible to remove the clause "that farm or farm under the same ownership" and improve readability. In order to increase understanding of the new definition and proposed reference to the "establishment" rather than relying on the overly narrow "ownership," it is important to provide a definition for "establishment." PDA proposes the following definition be added to the final regulation:

> *Establishment* means an organization, business, or group of entities operated under coordinated responsibility either by design or *de facto*, based on operational and functional control. An establishment may include multiple businesses and locations with varying ownership and operational models, but will be characterized by operating under coordinated management responsibility. An establishment's scope should be determined by evaluating the operational structure, business practices, ownership, the intent of the parties to the establishment, and other relevant factors.

PDA proposes the definition in order to offer clarification as to how an establishment will be determined between the regulator and the regulated entity and seeks FDA's recognition that the process of determining the scope of an establishment may not always be immediately clear. Further, in some situations, the process of determining the scope of an establishment may be done through exchange with the establishment owner/operator and evaluation of business documents and practices, and that this may also change if the establishment changes operations over time. An establishment should not be limited by "one geographic location," because evaluating establishments based on practices rather than on legal constructs will better protect public health and improve accountability.

PDA's objective in removing references to ownership and physical location is to ensure that we are able to work with the regulated community to implement practical approaches to compliance and improvements to public health. With the proposed modifications to the definition and the addition of the definition of establishment, the produce safety regulation will focus on improving the safety of produce grown and handled on farm businesses, as well as continue to recognize the evolving structure and organization of farms.

PDA supports the coordinated modifications to the definitions of covered activity, harvesting, holding, and packing to support the broader definition of farm. Each of these has been modified to no longer limit the activities to those "on that farm or another farm under the same ownership." The previous limitation created unrealistic and unnecessary limits on the definition of farm and farming activities. The new definitions reflect FDA's improved recognition that

regulating farm activities on the basis of ownership structures does little to improve public health.

2. Water Quality Standards

PDA Comment on Original Proposal

In the original produce safety proposal, PDA commented that complying with the water quality standards would be the single greatest obstacle to compliance. PDA suggested FDA wait to promulgate a water quality standard until research is performed and a standard is developed in accordance with food safety. We cited five major reasons to promulgate a water quality standard after further research, each of which we still support:

1. The current recreational water quality standards during growing activities for covered produce are unrelated to water use for food safety purposes;
2. By FDA's own admission, these numbers were selected as a close approximation;
3. It is more effective for FDA to conduct research related to agricultural water before setting a standard, rather than after a quasi-science supported standard is applied, as is currently proposed;
4. FDA is under a deadline to promulgate produce safety standards, but is NOT under a deadline specifically related to numeric water quality measures and relevant testing intervals (indicated by the delayed implementation of water standards);
5. Water quality standards will apply to produce offered for import. If the science used to establish these standards fails, the standards may be subject to challenge under the World Trade Agreements.

PDA Comments on the Supplemental proposal

PDA supports the proposed 112.44(a), which sets the standard for post-harvest activities, food contact surfaces, and all covered sprout activities at 0 generic *e. coli* / 100 mL, but does *not* support the water quality standard at 112.44(c) for growing activities, which incorporates the updated 2012 EPA Recreational Water Quality Standard. Although the recreational water quality standards is part of two separate produce safety programs for pre-harvest activities, adequate scientific evidence linking the recreational water quality standard to food safety does not exist, and FDA is under a statutory obligation to promulgate a science-based standard.

Previous produce safety programs have not been built on, or statutorily required to set a science-based standard for water quality, but the statutory language in § 419(a)(1)(A) requires "science-based minimum standards." Existing science to support the recreational water quality requirements has fallen far short of establishing a scientific connection between recreational water use and food safety for pre-harvest application to produce. Accordingly, PDA does not support applying the recreational water quality standard to the produce safety rule with respect to growing activities.

PDA suggests that although the proposed mitigation strategies represent an improvement in the overall agricultural water provisions, the standards for growing activities must be science based.

The standard included in the final regulation must be developed on the basis of meaningful data about produce safety and microbial survival rates on produce prior to harvest. Any standard that FDA promulgates not developed for food safety must be an interim standard and include a mandatory sunset within three or five years. Including a sunset in any standard allows FDA to establish a standard and recognize the EPA water quality information is less than ideal. The intervening years will also allow research institutions to work with FDA to develop a meaningful agricultural water standard.

PDA is concerned that setting a standard in the absence of scientific support would establish an arbitrary standard and be nearly impossible to update or change as adequate science became available. Accordingly, PDA suggests that FDA promulgate the final water quality standard with respect to 112.44(a) for post-harvest activities, but reserve the pre-harvest water quality standard until adequate research allows FDA to develop a pre-harvest standard associated with safety on growing activities.

Overarching Concern with the Complexity

The complexity of the water quality profile baseline survey, annual survey, recalculation indicators, and the calculations are too complicated. A water quality standard and testing interval should be designed in order allow regulated industry to readily understand the impact of any required calculation. FDA has not provided meaningful resources regarding actual samples and raw data in order to calculate a geometric mean (GM) and statistical threshold value (STV) accurately. Although limited materials have been available on the EPA website for recreational water quality standards, FDA's referenced sources have failed to provide meaningful information about the calculation process, nor provided raw data for commenters to use to confirm the accuracy of their own calculations.

It is PDA's hope that the absence of information forthcoming is recognition by FDA that the STV will not be included in the final water standard. A mere calculation tool will not be sufficient to educate the grower community in the public health importance of the STV.

While FDA attempted to provide flexibility in the supplemental rule for the purpose of water quality standards, the added flexibility is ambiguous. For surface water used for growing activities, developing a baseline survey over the course of two years and using five samples a year to verify the quality of the water, initially appears to provide flexibility because it allows implementation of mitigating strategies or treatment to occur between seasons, rather than in the middle of a season. However, the reliance on the calculation of twenty samples with a recalculation of the baseline could result in slower implementation of mitigating strategies, particularly with respect to permanently changed surface water.

Furthermore, the flexibility is not risk-based – farmers would potentially be spending valuable resources and time on testing when there is no scientific reason for the test. FDA must also recognize the difference in the way crops are grown and harvested across the U.S., recognizing regional differences.

3. Use of Raw Manure and Compost

PDA is supportive of the supplemental proposed rule changes to proposed 112.56, to reserve the application interval for untreated manure applied in a manner that does not contact covered produce during application and minimizes potential for contact after application (112.56(a)(1)(i)); and to reduce the application interval for composted manure that is applied to minimize potential for contact with covered produce during and after application to 0 days (112.56(a)(4)(i)). PDA strongly supports FDA's decision to wait until adequate science is developed to set an interval based on scientific data.

PDA supports applying the National Organic Program (NOP) standard of 90/120 days in the interim while research is performed to develop a standard. However, the NOP standard should not be codified. FSMA §419 required FDA to set science-based standards for food safety, but the NOP standard lacks a direct correlation to improving food safety.

In addition, PDA suggests that language be added in the final rule that would allow FDA flexibility to change biological soil amendment standards in the future as research evolves.

4. Domesticated and Wild Animals

Questions abound as to the actual and perceived scope of the risk from wildlife and other animals contacting produce. FDA should consider additional scientific studies and include provisions in the final rule that make clear the comparatively low and varying levels of risk posed by various animal species. Animal intrusions generally present a lower risk factor than those risks that may occur by other pathways and the probability for contamination differs based on the species of animal at issue.

PDA seeks clarification regarding what hazards FDA is seeking to control, so better and appropriate preventive controls can be developed to reduce the potential for contamination. Without a clear definition of the hazards required to be controlled, the ability of farmers and the state agencies to develop preventive controls is stymied.

Farm dogs and cats are frequently used as working animals on an operation (usually for pest control and/or keeping other animals out of fields and outbuildings). PDA seeks clarification and requests FDA verify that working animals are permitted if the farmer can demonstrate practices to reasonably minimize risk of excreta contaminating covered produce, with particular focus on reducing contact between domestic animals and covered produce after harvest.

The proposed rule can be interpreted to conflict with other federal programs to establish buffer zones and other natural vegetation buffer strips intended to improve water quality, protect endangered species, and enhance wildlife habitat. Farmers in other states are required to protect vegetation along fields for water quality and for endangered species habitat. USDA administers a conservation program through NRCS called the Wildlife Habitat Incentive Program (WHIP). It is a voluntary program for conservation-minded landowners who want to develop and improve wildlife habitat on agricultural land. FDA's requirement to restrict animals on agricultural lands

is in conflict with this important agricultural program. PDA requests that FDA provide information as to the perceived conflict of Subpart I with other conservation programs.

This concludes the Pennsylvania Department of Agriculture's comments on the Draft Environmental Impact Statement for the proposed rule establishing standards for the growing, harvesting, packing, and holding of produce for human consumption. I appreciate the opportunity to provide comments and look forward to continuing dialogue with the FDA prior to the release of the final rule.

Sincerely,

Russell C. Redding

Russell C. Redding
Acting Secretary

cc: Dr. Stephen Ostroff, Acting Commissioner, FDA

PUBLIC SUBMISSION

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Tracking No. 1jz-8hpd-zrla
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Docket: FDA-2014-N-2244
Environmental Impact Statement (EIS) for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Comment On: FDA-2014-N-2244-0007
Draft Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Notice for Public Meeting on Draft Environmental Impact Statement

Document: FDA-2014-N-2244-DRAFT-0374
Comment from Anjali Sarath, NA

Submitter Information

Name: Anjali Sarath
Address: 90602
Email: anjali.sarath09@gmail.com
Organization: NA

General Comment

It is widely accepted that contamination of agricultural produce can occur at any time before it reaches consumers. While there are many regulatory processes in place to prevent any mishaps, they sometimes prove burdensome to farmers and businesses and may cause a lack of adherence leading to major public safety issues. However, Proposed Rule - Draft Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (hereafter referred to as Proposed Rule) would make it easier for farmers and producers to effectively monitor microbial contamination of their produce before it is harvested. As a customer of organic produce, one considers the standards in the Proposed Rule for Biological Soil Amendments (BSA) of animal origin especially important. The term "organic" often leads customers to place a great deal of trust in the produce with respect to it being safe for human consumption. This is based on the perceptions that pesticides and other chemicals are absent on organic produce; the microbial safety of the food is rarely considered. While one acknowledges that small-scale organic farmers may find it stifling to follow more regulations, the new standards, if implemented, would ensure public safety without causing much distress to farmers. It is important to have a long enough interval between the application of manure and the harvesting of crops. As long as the microbial safety can be scientifically analyzed and monitored, the decision to defer the nine-month-long interval will be beneficial for

farmers who cultivate time-sensitive crops. One wishes to promote such standards, and recommends that the standard reflect the USDAs National Organic Program standards, which call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for crops not in contact with the soil. However, if the minimum 45-day application interval were to be lifted for compost, it is recommended that measures be implemented to ensure that composted soil is properly treated to avoid public health mishaps. Furthermore, making the standards for water quality and testing more flexible has to make provisions for a better environment for farmers to comply with public health safety guidelines with respect to microbial risks. As recommended by many commenters allowing for a die-off period for microbes before the crops are harvested will be an effective measure to ensure public health safety. This commenter expresses support for the standards in the Proposed Rule, provided that no compromises are made on public health safety, and that measures in place that monitor microbial contamination after harvest are also strictly enforced.

Division of Dockets Management (HFA-305),
Food and Drug Administration,
5630 Fishers Lane, Rm. 1061,
Rockville, MD 20852.

RE: Comments on Docket Number# FDA-2014-N-2244, FDA's Draft Environmental Impact Statement (EIS) for the proposed rule establishing standards for the growing, harvesting, packing, and holding of produce for human consumption.

March 10, 2015

Dear Federal Drug Administration:

We respectfully submit these comments in response to the EIS for the proposed rule establishing standards for the growing, harvesting, packing, and holding of produce for human consumption. My comments concerning these important rules are as follows:

While the EIS acknowledges that "Native American Tribes may be disproportionately impacted" by groundwater draw down, the EIS does not mention any Tribe specifically nor does it acknowledge other impacts that will affect tribes such as land use or land management, water rights, or treaty rights. There are over 565 Tribes in the United States, with unique self-governments, land status, many of which may be affected in many other ways than just by ground water draw down. A more thorough analysis should be given to the unique water rights and water law issues pertaining to Tribes, rather than mentioning Tribes in a general context. While the EIS does attempt to delve into the impacts on tribes through an cursory analysis of the Census of Agriculture as it reports American Indian, Alaska Native and Native Hawaiian producers, the EIS acknowledges the inadequacy of the data and the inability of the EIS to analyze the true impacts on tribes(p. 3-153). Figure 3.7-6 attempts to help narrow down regions where tribal lands could be impacted by the PS PR, but the figure is misguided. Tribal lands impacted by PS PR are much more wide spread than the figure within the EIS acknowledges. (p.3-154)

The EIS does mention the 566 tribes. On page 3-147, the EIS states "There are currently 566 federally recognized tribes located in the United States, with reservations and tribal lands throughout the United States (Figure 3.7-4) each with a wide array of interests and issues which may or may not be relevant or of concern to other tribes." The issue is not whether the interest and issues which may or may not be relevant or of concern to all tribes, the issue is how these new regulations will affect each of the 565 Tribes and how those affects will be of issue to the Federal Government and its agencies vis-à-vis its trust relationship with tribes.

Furthermore, the EIS states that "For purposes of the Environmental Justice review, tribal populations are considered part of the total minority population." The EIS inadvertently diminishes decades of Federal law that explicitly define Tribes as self-governing nations with corresponding Executive Orders (E.O 13175 and the

reaffirmation of that order through Presidential Memorandum of November 2009) that requires Tribal consultation because of Tribes' unique political status. The recognition in federal law of Tribes' unique political status should be tempered within their treatment as "part of the total minority population" and any environmental justice-focused analysis must take into account that unique political status.

The EIS further diminishes Tribal status in its summary and conclusion sections when it says, "The majority of the environmental issues would affect a tribal entity are the same as it would affect any minority property owner (p-3-156)." This statement is untrue and unprecedented. Tribes are more than minority property owners. They are self-governing entities that have autonomous governments with ability and authority to create laws and regulations that govern land management, business relationships, and their people. Land management, business relationships and people will be affected by each section of proposed rules and to summarily reflect that the majority of issues will affect tribes in the same way as any other minority property owner is to discount their political status, but also to discount the unique land tenure status and litigated water rights relationships only tribes possess, in contrast to any other minority property owner. Unless the status of Tribes is recognized and Executive Order 13175 and the Presidential Memorandum of November 2009 honored, the EIS will continue to fail to address the impacts on Tribal Nations.

Lastly, the FDA lists tribal individuals as participants in its tribal consultation list. Tribal Consultation is not meant to address Tribal individuals or even nonprofit organizations run by groups of tribal individuals, but tribal governments, of which very few are listed. An individual's tribal affiliation does not negate an agency's responsibility to engage Tribal governments in tribal consultation. For instance, an agricultural lawyer with Tribal membership may not be officially recognized to speak on behalf of her Tribal Nation. Tribal governments can only be represented by official tribal leadership or duly authorized representatives. To paint a true picture of Tribal Consultation, it may be more effective to list Tribal governments and their official representatives and/or leadership. Merely listing a group of Tribal members who participated in phone calls or webinars and to expect that participation to count as true Tribal Consultation as ordered by the Executive Office of multiple Presidents is wholly inadequate.

The draft EIS is a start, particularly in its attempt to address tribal specific data in the Agricultural Census, but the EIS is not complete without a more thorough Tribal consultation process delineated and accomplished. It is highly recommended that language that diminishes Tribal Nation status to that of minority farmers be changed to adhere to Federal law that recognizes tribes as governments.

Thank you for accepting these comments and we look forward to a response,

Janie Simms Hipp, J.D., LL.M.
921 Vandeventer
Fayetteville, AR 72701

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Docket No. FDA–2014–N–2244
RIN 0910-AG35

Submitted electronically at: http://www.regulations.gov.

Re: Comment on the U.S. Food and Drug Administration's Draft Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

To the U.S. Food and Drug Administration:

The Urban Farming Institute of Boston is pleased to provide comments on the Draft Environmental Impact Statement for the Proposed Rule on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, being issued by the Food and Drug Administration (FDA) pursuant to the Food Safety and Modernization Act of 2011 (FSMA). We appreciate that FDA recognized the need to prepare an environmental impact statement. This comment discusses several issues in the draft EIS that we urge FDA to address in the final rule related to the Environmental Impact Statement.

The Urban Farming Institute of Boston. As pioneers in urban agriculture, the Urban Farming Institute of Boston (UFI) has a unique perspective on the impact of the supplemental proposed rules on small urban farmers. A Massachusetts grass-roots non-profit community-based organization, UFI focuses on developing urban farming as a viable commercial industry that creates green-collar jobs for local residents in communities of color. Through hands-on courses on farming theory, entrepreneurship, how to purchase and plant seeds, and how to sell produce to commercial and retail buyers, UFI trains individuals to become successful urban farmers, assisting them to acquire and remediate land to make suitable for farming small urban plots that have remained vacant and unproductive for decades. Through conferences and community outreach, UFI educates community, city, and state stakeholders to make appropriate policy changes in land use to support urban farming as a sustainable agricultural model with capacity to contribute local healthy fresh food to underserved communities. Through research and analysis, UFI influences local, state, and national policy on food security and urban farming by documenting the impact of urban agriculture on the social, economic, and health outcomes for its practitioners and the communities they serve.

UFI has collaborative relationships with a wide range of public and private entities as well as individuals committed to promoting citizen involvement with the production of healthy food and sustainable agriculture, including state and local governments, conservation land trusts, community-based organizations, foundations,

private philanthropists, city planners, educators, economic and community developers. Among those are the Massachusetts Department of Agricultural Resources, the Massachusetts Food Policy Council, the Boston Redevelopment Authority, the Boston Division of Neighborhood Development, the Food Project, the Trust for Public Land, the Trustees of Reservations, and the Kendall Foundation. More information about UFI's mission can be found at http://urbanfarminginstitute.wordpress.com/.

We provide comments below on the Draft Environmental Impact Statement (EIS) for the Proposed Rule on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (the Produce Safety Rule). Aware that the FDA reviewers are very familiar with the provisions of FSMA as well as the provisions of the proposed rules, in the interest of simplicity and brevity, we have omitted quotes and citations. Because of the complexity of the proposed rules and our limited resources for our own detailed analysis, we have relied to a great extent on the very thorough and insightful comments of the Conservation Law Foundation (CLF). We urge the FDA to review carefully CLF's comments, as well as the comments from the National Sustainable Agriculture Coalition. We also urge the FDA to adopt the recommendations of these organizations as the voices of the small farmers and food processors who are too overwhelmed with the everyday work on the farm to be able to wade through pages of proposed federal regulations and to write detailed comments.

I. FDA Should Identify and Incorporate into the Final EIS More Robust Data that Allows Study of Local Environmental Impacts.

The draft EIS addresses many salient impacts under the proposed Produce Safety Rule that could significantly affect the quality of the human environment. However, several times FDA claims that insufficient data exists to identify local environmental impacts of the PSR. FDA states that the focus in the draft EIS is on regional and national environmental impacts, not local. However, the impacts at the local level are potentially significant not only because of the effects on that particular area, but also because of cumulative effects at the regional or national levels.

FDA clearly acknowledges the possibility that some farms, particularly very small or small farms—even if exempted from the rule—may be forced to change crops grown or stop growing crops altogether. But the draft EIS does not fully assess these impacts either at the local level or in the aggregate. Existing information can provide FDA with sufficient data to project with more specificity the possible environmental impact at the local level.

The loss to communities throughout New England of multiple smaller farms being required to significantly change operations or stop growing could produce a significant environmental effect in that region and beyond. Inevitably, the production burden will increasingly shift to large-scale farms located primarily in California where water resources are already being pushed to a breaking point.

We urge FDA to include in the final EIS a more robust study of the impact under Subpart A of potentially removing smaller farms from production.

II. The Final EIS Should Analyze the Reasonable Alternative of Including the Concept of Co-management Directly in the Text of the Produce Safety Rule in Subpart I.

FDA acknowledges the beneficial impact of co-management measures on wildlife and the farm environment. These practices can mitigate potentially adverse impacts to habitat. Nonetheless, neither the Produce Safety Rule as proposed nor the draft EIS considers the reasonable alternative of explicitly affirming in the language of the proposed rule that farmers may use co-management practices.

As FDA recognizes in the preamble to the proposed Produce Rule and in the draft EIS, co-management is an important tool for farms to use to manage wildlife and the health of the farm environment. In fact, National Organic Program regulations require organic operators to maintain or improve natural resources. These regulations define organic production as a system that integrates cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity. If FDA does not protect the right of organic growers to use practices that co-manage for conservation and food safety, it will be actively constraining growers from becoming certified organic and risk impairing the ability of existing organic growers to stay certified. It is critical, therefore, that FDA analyze in the final EIS the reasonable alternative of explicitly affirming in the proposed rule that farmers *may use* co-management practices.

III. FDA Must Analyze the Preventive Controls Rule as a Connected Action in the Final EIS.

The draft EIS analyzes the Preventive Controls Rule for Human Food (the Preventive Control Rule) in terms of its potential cumulative impacts. FDA concludes that the cumulative impacts of the Produce Controls Rule are not significantly adverse. This conclusion implicitly relies on the assumption that the Produce Controls Rule is not a connected action under the National Environmental Policy Act that must be analyzed as such in the EIS. As a result, FDA has failed to fully examine the Produce Controls Rule's potential effects. There is no doubt that the Produce Safety Rule and the Preventive Controls Rule are connected and must be considered together in the EIS. The rules are interdependent, and they both implement FSMA—the larger action. They also clearly depend on FSMA for their justification. The proposed rules share several definitions and frequently cross-reference each other. FDA cannot adequately assess the full impact of the proposed PSR's effects on the human environment without simultaneously analyzing the effects of the proposed PCR.

Numerous farms, particularly smaller, diversified produce farms in New England increasingly rely on on-farm "processing" of food to add value to their operations. Those activities may subject the farms to both rules. Conducting an EIS for the Produce Safety

Rule alone underestimates the potentially significant environmental effects of both rules. We therefore submit that FDA must analyze the impacts of the Preventive Controls Rule and the Produce Safety Rule in the final EIS.

Conclusion. We appreciate the opportunity to submit this comment on the Produce Safety Rule draft Environmental Impact Statement and urge FDA to consider our recommendations in the final EIS. Again, we urge you to consider and adopt the recommendations of the Conservation Law Foundation and the National Sustainable Agriculture Coalition.

Sincerely,

Patricia E. Spence
Executive Director
Urban Farming Institute

March 13, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Docket No. FDA–2014–N–2244
RIN 0910-AG35

Submitted electronically at: http://www.regulations.gov.

Re: Comment on the U.S. Food and Drug Administration's Draft Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

To the U.S. Food and Drug Administration:

Thank you for the opportunity to comment under the National Environmental Policy Act (NEPA) on the draft Environmental Impact Statement (EIS) for the Produce Safety Rule (PSR). We appreciate that FDA recognized the need to prepare an EIS. This comment discusses several issues in the draft EIS that we urge FDA to address in the final EIS. We also incorporate herein by reference the comment on the draft EIS prepared by the National Sustainable Agriculture Coalition.

ABOUT CONSERVATION LAW FOUNDATION

Conservation Law Foundation (CLF) uses the law, science, policymaking, and the business market to find pragmatic, innovative solutions to New England's environmental problems. CLF's Farm and Food Initiative works to create a robust regional food system across New England. Sustainable agriculture is vital for building resilience to climate change, conserving land, and creating a healthy, economically vibrant New England. Our Farm and Food Initiative provides legal, policy, and market-based strategies to advance sustainable agriculture at the local and regional scale. To learn more about our work, please visit http://www.clf.org/our-work/healthy-communities/farm-and-food-initiative/.

ABOUT THE FOOD PROJECT

The Food Project's mission is to create a thoughtful and productive community of youth and adults from diverse backgrounds who work together to build a sustainable food system. Our community produces healthy food for residents of the city and suburbs, provides youth leadership opportunities, and inspires and supports others to create change in their own communities.

ABOUT THE URBAN FARMING INSTITUTE OF BOSTON

The Urban Farming Institute's (UFI) mission is to contribute to healthy people and sustainable cities by promoting and creating self-sustaining urban farming enterprises and farming jobs. By enabling urban farming through farm creation, farmer training, public education and policy change, UFI brings people in urban neighborhoods closer to food production.

* * * * *

COMMENT

I. FDA Should Identify and Incorporate into the Final EIS More Robust Data that Allows Study of Local Environmental Impacts.

The draft EIS addresses many salient impacts under the proposed Produce Safety Rule that could significantly affect the quality of the human environment. However, several times FDA claims that insufficient data exists to identify local environmental impacts of the PSR.[1] When discussing Subpart A, which includes discussion of potential impacts of the rule based on who is subject to the requirements of part 112, FDA states that the focus in the draft EIS is on regional and national environmental impacts, not local.[2] The impacts at the local level are potentially significant not only because of the effects on that particular area, but also because of cumulative effects at the regional or national levels. Moreover, sufficient data does exist—albeit sometimes at the state or local level—from which FDA can at least extrapolate local impacts.

Council on Environmental Quality regulations call for properly evaluating the impact of the proposed action on "society as a whole . . . , the affected region, the affected interest, and the locality."[3] By confining analysis in the draft EIS to the regional and national levels and failing to simultaneously analyze how impacts on very small and small farms that may qualify for certain exemptions might—in the aggregate—have significant effects on a broader scale, FDA has not adequately assessed the potential impact of the rule on the human environment.

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[1] *See, e.g.*, Draft Environmental Impact Statement (EIS) for the Proposed Rule: Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, at 4-79, Food and Drug Administration (Jan. 9, 2015) ("FDA is not evaluating the potential environmental impacts at the local level as part of this EIS; rather it is focused in regional and national environmental impacts.").
[2] *Id.* at ES-7.
[3] 40 C.F.R. § 1508.27.

FDA clearly acknowledges the possibility that some farms, particularly very small or small farms—even if exempted from the rule—may be forced to change crops grown or stop growing crops altogether.[4] But the draft EIS does not fully assess these impacts either at the local level or in the aggregate. In fact, FDA references local impacts only when analyzing the impact that the agricultural water standard may have on some operations. Even in this short analysis in chapter 4.2, however, FDA concludes that insufficient data exists to quantify or qualify the effects of farms changing crops grown or ceasing to grow at all. We understand that FDA is challenged by certain data limitations. Nonetheless, FDA can and must fulfill its statutory obligation under NEPA.

Existing information can provide FDA with sufficient data to project with more specificity the possible environmental impact at the local level. As a starting point, FDA can make some of these projections based on the 2012 Census of Agriculture. Beyond that, state departments of agriculture, many not-for-profit organizations, and some for-profit groups (such as those conducting GAP audits) can give FDA enough information on which to make predictions about the impacts of the rule at the local level. NEPA requires that FDA provide at least some attempt to assess such local impacts in the EIS.[5]

The loss to communities throughout New England of having multiple smaller farms significantly change operations or stop growing could produce a significant environmental effect in that region and beyond. Inevitably, the production burden will increasingly shift to large-scale farms located primarily in California where water resources are already being pushed to a breaking point.[6]

We urge FDA to include in the final EIS a more robust study of the impact under Subpart A of potentially removing smaller farms from production.

II. The Final EIS Should Analyze the Reasonable Alternative of Including the Concept of Co-management Directly in the Text of the Produce Safety Rule in Subpart I.

FDA acknowledges the beneficial impact of co-management measures on wildlife and the farm environment.[7] These practices can mitigate potentially adverse impacts on habitat. Nonetheless, neither the PSR as proposed nor the draft EIS considers the reasonable alternative of explicitly affirming in the language of the proposed rule that farmers may use co-management practices.

Pursuant to NEPA, consideration of alternatives to the proposed action is the "heart of the environmental impacts statement."[8] FDA must discuss all "reasonable" alternatives in the EIS.[9]

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[4] *See* DEIS, *supra* note 1, at 4-28 to 4-29.
[5] *See* 40 C.F.R. § 1508.27.
[6] *See e.g.*, draft EIS, *supra* note 1, at 1-23 (Fig. 1.7-4), 3-14, 3-20.
[7] *Id.* at 4-74 to 4-75.
[8] 40 C.F.R. § 1502.14; *see also Monroe County Conservation Council, Inc. v. Volpe*, 472 F.2d 693, 697–98 (2d Cir. 1972) (describing the alternatives analysis as the "linchpin" of the EIS)

An agency must consider alternatives to the proposed action that might present a more environmentally sustainable project.[10] Analysis must include "the full range of direct, indirect, and cumulative effects of the [proposed project itself] and of the reasonable alternatives identified in the draft EIS."[11] A project's purpose and need define the scope of reasonable alternatives that FDA must consider.[12] As part of the EIS process mandated by NEPA, the agency must take a "hard look" at all impacts of and potential alternatives to the proposed action.[13]

As FDA recognizes in the preamble to the proposed Produce Rule and in the draft EIS, co-management is an important tool for farms to use to manage wildlife and the health of the farm environment.[14] In fact, National Organic Program regulations require organic operators to maintain or improve natural resources.[15] These regulations define organic production as a system that integrates cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.[16] If FDA does not protect the right of organic growers to use practices that co-manage for conservation and food safety, it will be actively constraining growers from becoming certified organic and risk impairing the ability of existing organic growers to stay certified. It is critical, therefore, that in the final EIS FDA analyze the reasonable alternative of explicitly affirming in the proposed rule that farmers *may use* co-management practices.

III. FDA Must Analyze the Preventive Controls Rule as a Connected Action in the Final EIS.

The draft EIS analyzes the Preventive Controls Rule for Human Food (PCR) in terms of its potential cumulative impacts.[17] FDA concludes that the cumulative impacts of the PCR are not significantly adverse.[18] This conclusion implicitly relies on the assumption that the PCR is not a connected action under NEPA that must be analyzed as such in the EIS. As a result, FDA has failed to fully examine the PCR's potential effects.

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[9] *NRDC v. Morton*, 458 F.2d 827, 834 (D.C. Cir. 1972).
[10] *See Calvert Cliffs' Coordinating Committee, Inc. v. Atomic Energy Commission*, 449 F.2d 1109, 1114 (D.C. Cir. 1971) (explaining that only by considering alternatives can the agency make "the most intelligent, optimally beneficial decision").
[11] COUNCIL ON ENVIRONMENTAL QUALITY, EXEC. OFFICE OF THE PRESIDENT, A CITIZEN'S GUIDE TO THE NEPA: HAVING YOUR VOICE HEARD, at 17 (2007).
[12] 40 C.F.R. § 1502.13; *Friends of Southeast's Future v. Morrison*, 153 F.3d 1059, 1065 (9th Cir. 1998) ("The agency must look at every reasonable alternative within the range dictated by the nature and scope of the proposal.").
[13] 42 U.S.C. § 4332(2)(C); *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989) (quoting *Kleppe v. Sierra Club*, 427 U.S. 390, 410 n.21 (1976)).
[14] *See, e.g.*, DEIS, *supra* note 1, at 1-19, 4-74 to 4-75.
[15] 7 C.F.R. §§ 205.200, 205.2.
[16] *Id.* § 205.2.
[17] draft EIS, *supra* note 1, at 5-1, 5-3, 5-14 to 5-15.
[18] *Id.* at 5-15.

Under NEPA, actions are connected or closely related if, among other things, they are "interdependent parts of a larger action and depend on the larger action for their justification."[19] Connected actions must be discussed in the same EIS.[20] There is no doubt that the PSR and PCR are connected and must be considered together in the EIS. The rules are interdependent, and they both implement FSMA—the larger action. They also clearly depend on FSMA for their justification. The proposed rules share several definitions and frequently cross-reference each other. FDA cannot adequately assess the full impact of the proposed PSR's effects on the human environment without simultaneously analyzing the effects of the proposed PCR.

Numerous farms, particularly smaller, diversified produce farms in New England increasingly rely on on-farm "processing" of food to add value to their operations. Those activities may subject the farms to both rules. Conducting an EIS for the PSR alone (with only scant mention of the PCR) underestimates the potentially significant environmental effects of both rules. We therefore submit that FDA must analyze the impacts of the PCR and the PSR in the final EIS.

CONCLUSION

We appreciate the opportunity to submit this comment on the Produce Safety Rule draft Environmental Impact Statement and urge FDA to consider our recommendations in the final EIS. If you have any questions about this comment, please contact Ben Tettlebaum at (207) 210-6439 x5014.

Sincerely,

Ben W. Tettlebaum	Patricia E. Spence	John Harrison
Rhodes Fellow/Attorney	Executive Director	Executive Director
Conservation Law Foundation	Urban Farming Institute of Boston	The Food Project

[19] 40 C.F.R. § 1508.25(a); *see Theodore Roosevelt Conservation P'ship v. Salazar*, 616 F.3d 497, 514 (D.C. Cir. 2010) (citing *Kleppe v. Sierra Club*, 427 U.S. 390, 410, (1976)); *Kern v. U.S. Bureau of Land Mgmt.*, 284 F.3d 1062, 1077 (9th Cir. 2002) (citation and internal quotation marks omitted).

[20] *See Theodore Roosevelt Conservation P'ship*, 616 F.3d at 514; 40 C.F.R. § 1508.25(a).

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Environmental Impact Statement (EIS) for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Comment On: FDA-2014-N-2244-0007
Draft Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Notice for Public Meeting on Draft Environmental Impact Statement

Document: FDA-2014-N-2244-DRAFT-0366
Comment from Stephanie Ugalde, CSULA

Submitter Information

Name: Stephanie Ugalde
Organization: CSULA

General Comment

This is interesting that you decide to implement proposed rule establishing standards for the growing, harvesting, packing, and holding of produce for human consumption. This will allow safer consumption for said products. I myself am glad to see that there is change being made and standards willing to be upheld. It is about time that more steps are being made. My concern, however, lies in the subject of enforcing these standards. No matter how many rules, guidelines, laws are lain down, unless harder regulations are put down, corners will be cut through the fact of cost and time consumption. Just because you lay down a rule does not mean that the people who are actually going to be in charge of abiding by the rule know just how much of an importance it is. So it is of utmost importance to provide education as to why these rules are being put in place, why this is better, how it is beneficial. Perhaps also trying to take these rules and applying it to commerce. How much of our food is also outsourced? When thinking about that, think about the food-borne illnesses that pose with those products. Just how much food are we importing and contain a virus like hepatitis A? China has poor water sanitation. We get some of our products from China. And just this year, an HAV outbreak occurred from berries originating from China due to poor hygiene and water supply. We need stricter rules, better incentives, and spread education.

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APPENDIX F

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 2 6 2015

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

Annette McCarthy, Ph.D.
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740

Dear Dr. McCarthy:

In accordance with our authorities under the National Environmental Policy Act (NEPA) and Section 309 of the Clean Air Act, EPA has reviewed the draft Environmental Impact Statement (DEIS) developed by the U.S. Food and Drug Administration (FDA) on its Produce Safety Proposed Rule (PSPR) for *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.*

The purpose of this rule is to minimize the risk of serious adverse health consequences or death from the introduction of known or reasonably foreseeable biological hazards into or onto produce. The rule includes requirements to prevent such occurances and to provide reasonable assurances that produce is not adulterated on account of such hazards.

EPA believes that the DEIS provides an adequate discussion of the potential environmental impacts of the proposed rule and we have not identified any potential environmental impacts requiring substantive changes. EPA has rated the draft EIS as LO – "Lack of Objections;" a summary of EPA's rating is enclosed.

Please feel free to contact me or have your staff contact Cliff Rader, Director, NEPA Compliance Division, at (202)-564-7159 if you have any questions or would like to discuss our comments.

Sincerely,

Susan E. Bromm

Susan E. Bromm
Director
Office of Federal Activities

Enclosure

Summary of Rating Definitions and Follow-up Action

Environmental Impact of the Action

LO--Lack of Objections
The EPA review has not identified any potential environmental impacts requiring substantive changes to the proposal. The review may have disclosed opportunities for application of mitigation measures that could be accomplished with no more than minor changes to the proposal.

EC–Environmental Concerns
The EPA review has identified environmental impacts that should be avoided in order to fully protect the environment. Corrective measures may require changes to the preferred alternative or application of mitigation measures that can reduce the environmental impact. EPA would like to work with the lead agency to reduce these impacts.

EO--Environmental Objections
The EPA review has identified significant environmental impacts that must be avoided in order to provide adequate protection for the environment. Corrective measures may require substantial changes to the preferred alternative or consideration of some other project alternative (including the no action alternative or a new alternative). EPA intends to work with the lead agency to reduce these impacts.

EU--Environmentally Unsatisfactory
The EPA review has identified adverse environmental impacts that are of sufficient magnitude that they are unsatisfactory from the standpoint of public health or welfare or environmental quality. EPA intends to work with the lead agency to reduce these impacts. If the potentially unsatisfactory impacts are not corrected at the final EIS stage, this proposal will be recommended for referral to the CEQ.

Adequacy of the Impact Statement

Category 1--Adequate
EPA believes the draft EIS adequately sets forth the environmental impact(s) of the preferred alternative and those of the alternatives reasonably available to the project or action. No further analysis or data collection is necessary, but the reviewer may suggest the addition of clarifying language or information.

Category 2--Insufficient Information
The draft EIS does not contain sufficient information for EPA to fully assess environmental impacts that should be avoided in order to fully protect the environment, or the EPA reviewer has identified new reasonably available alternatives that are within the spectrum of alternatives analyzed in the draft EIS, which could reduce the environmental impacts of the action. The identified additional information, data, analyses, or discussion should be included in the final EIS.

Category 3–Inadequate
EPA does not believe that the draft EIS adequately assesses potentially significant environmental impacts of the action, or the EPA reviewer has identified new, reasonably available alternatives that are outside of the spectrum of alternatives analyzed in the draft EIS, which should be analyzed in order to reduce the potentially significant environmental impacts. EPA believes that the identified additional information, data, analyses, or discussions are of such a magnitude that they should have full public review at a draft stage. EPA does not believe that the draft EIS is adequate for the purposes of the NEPA and/or Section 309 review, and thus should be formally revised and made available for public comment in a supplemental or revised draft EIS. On the basis of the potential significant impacts involved, this proposal could be a candidate for referral to the CEQ.